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SUPREME COURT

OF THE

STATE OF CONNECTICUT

S.C. 20765

KRISTIN MILLS, ADMINISTRATOR (ESTATE OF CHERYL MILLS)
Plaintiff-Appellee

v.

HARTFORD HEALTHCARE CORPORATION ET AL.
Defendants-Appellants

Brief of Defendants-Appellees Asad Rizvi, M.D. and Hartford Healthcare Corporation

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Filed: January 23, 2023

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STATEMENT OF THE ISSUES

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2. Did the Trial Court correctly determine that the Defendants were entitled to immunity under the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. § 247-6d *et seq*. (pages 33–36)?
3. If the Defendants are not entitled to immunity under the PREP Act, did Plaintiff adequately plead "gross negligence" (pages 37–39)?
4. Did the Trial Court properly decide the Defendants' entitlement to immunity where Plaintiff did not dispute with evidence the facts regarding how COVID-19 affected the decedent's care (pages 39–41)?

1. INTRODUCTION

As part of the State's response to the COVID-19 pandemic, which was focused on containing the spread of COVID-19, Hartford Healthcare enacted protocols that required its doctors to restrict certain treatments to individuals who had a clinical need for them. Hartford Healthcare did that to, among other things, preserve vital personal protective equipment ("PPE") and minimize exposing staff and patients to COVID-19. Those protocols were particularly strict with respect to known or suspected COVID-19 patients.

Pursuant to those protocols and his suspicion that the decedent's (Ms. Mills') symptoms were caused by COVID-19 instead of a heart attack, a doctor personally examined Plaintiff's mother, Ms. Mills, to determine whether she was more likely having a heart attack or heart inflammation caused by COVID-19. The doctor concluded that Ms. Mills was more likely having heart inflammation than a heart attack, and the hospital's COVID-19 policies therefore precluded the doctor from sending Ms. Mills for further treatment until she tested negative.

Plaintiff claims that the doctor's conclusion was wrong, but has never disputed the fact that the conclusion was required by COVID-19 protocols and the need, consistent with the State's containment strategy for COVID-19, to slow the spread of the pandemic. Nor has Plaintiff ever meaningfully disputed that the doctor's conclusion was otherwise materially affected by COVID-19 and COVID-19 protocols.

The Trial Court correctly concluded that the Defendants were therefore entitled to immunity provided by Governor Lamont to health care professionals and facilities for acts in support of the State's COVID-19 response and the federal PREP Act.

Plaintiff challenges that conclusion, but her arguments fail because she cannot dispute that the doctors' actions were part of the State's COVID-19 response and that COVID-19 affected their opinions.

2. FACTUAL BACKGROUND

A. Governor Lamont's Response To COVID-19

On March 10, 2020, Governor Lamont declared a public health emergency in response to the COVID-19 pandemic. *See, e.g.*, *Casey v. Lamont*, 338 Conn. 479, 483, 258 A.3d 647, 650 (2021). In so doing, Governor Lamont explained that "COVID-19 is a respiratory disease that spreads easily from person to person" and that "public health experts have indicated that persons infected with COVID-19 may not show symptoms, and transmission or 'shedding' of the coronavirus that causes COVID-19 may be most virulent before a person shows any symptoms." *Fay v. Merrill*, 336 Conn. 432, 437 n.7, 246 A.3d 970, 975 (2020) (quoting Governor Lamont). "The United States Centers for Disease Control and Prevention [the "CDC"] 'recommended that people with mild symptoms consistent with COVID-19 be assumed to be infected with the disease,' and 'public health experts . . . recommended that, to prevent transmission of COVID-19, and in light of the risk of asymptomatic transmission and a significant rate of false negative test results, everyone should assume they can be carrying COVID-19 even when they have received a negative test result or do not have symptoms.'" *Id.* (quoting the CDC) (alterations omitted). Governor Lamont adopted those principles in his pandemic Executive Orders.[1]

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[1] *See, e.g.*, Executive Order 7QQ ("[T]he CDC has recommended that people with mild symptoms consistent with COVID-19 be assumed to be infected with the disease[] and . . . public health experts have recommended that, to prevent transmission of COVID-19, and in light of the risk of asymptomatic transmission and a significant rate of false negative tests, everyone should assume they can be carrying COVID-19 even when [they] have received a negative test result or do not have symptoms[.]").

Governor Lamont also "promulgated a series of executive orders in an attempt to contain and mitigate the spread of COVID-19." *Casey*, 338 Conn. at 484. As directly relevant here, he issued Executive Orders 7U and 7V (the "Executive Orders" or "Executive Orders 7U & 7V").[2] Through Executive Orders 7U & 7V, Governor Lamont sought, among other things, to (1) expand the size of the State's health care workforce so that it could better respond to the pandemic and (2) encourage health care workers to take actions necessary to treat and protect patients during the pandemic even if health care workers would not ordinarily take those actions.[3] Governor Lamont determined that it was necessary to confer immunity on health care professionals and facilities in order to achieve those goals.[4]

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[2] Governor Lamont issued Executive Orders 7U & 7V after the events underlying this case, but Executive Orders 7U & 7V apply retroactively to those events. (*See* Executive Orders 7U & 7V.)

[3] *See, e.g.*, Executive Order 7U ("WHEREAS, in order to respond adequately to the public health emergency posed by the COVID-19 pandemic, it has been necessary to supplement Connecticut's health care workforce and the capacity of health care facilities to deliver life-saving care by . . . calling upon healthcare professionals to perform acts that they would not perform in the ordinary course of business[.]"); Executive Order 7V ("WHEREAS, there exists a compelling state interest in rapidly expanding the capacity of health care professionals and facilities to provide care during the COVID-19 pandemic[.]").

[4] *See, e.g.*, Executive Order 7U ("WHEREAS, in order to encourage maximum participation in efforts to [] expand Connecticut's health care workforce and facilities capacity, there exists a compelling state interest in affording such professionals and facilities protection against

> Governor Lamont therefore provided that
> [A]ny health care professional or health care facility shall be immune from suit for civil liability for any injury or death alleged to have been sustained because of the individual's or health care facility's acts or omissions undertaken in good faith while providing health care services in support of the State's COVID-19 response, including but not limited to acts or omissions undertaken because of a lack of resources[] attributable to the COVID-19 pandemic . . . .

(Executive Orders 7U & 7V.[5])

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liability for good faith actions taken in the course of their significant efforts to assist in the state's response to the current public health and civil preparedness emergency[.]"); Executive Order 7V ("WHEREAS, providing relief from liability for such health care professionals for good faith efforts to provide care during the COVID-19 pandemic will greatly increase the state's ability to achieve [] an expansion[.]").

[5] The immunity provisions in Executive Orders 7U & 7V are identical, except that Executive Order 7V broadens the scope of immunity by applying immunity to common law claims. (Executive Order 7V.)

Governor Lamont used very broad definitions of "health care professional"[6] and "health care facility"[7] in the Executive Orders.[8]

B. Hartford Healthcare Prepares For And Responds To The Pandemic

Hartford Healthcare took steps to ensure that it would be able to continue to provide advanced care despite the challenges imposed by the pandemic. (*See, e.g.*, RA62–63.[9]) For example, to ensure that care would not be adversely impacted, Hartford Healthcare took "various

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[6] *See* Executive Orders 7U & 7V (defining "health care professional" as "an individual who is licensed, registered, permitted, or certified in *any state* in the United States to provide health care services and *any retired* professional, professional with an inactive license, *or volunteer* approved by the Commissioner of the Department of Public Health or her designee" (emphasis added)).

[7] *See* Executive Orders 7U & 7V (defining "health care facility" as "a licensed or state approved *hospital, clinic, nursing home, field hospital or other facility* designated by the Commissioner of . . . Public Health for temporary use for the purpose of providing essential services in support of the State's COVID-19 response" (emphasis added)).

[8] It is undisputed that Defendants meet these expansive definitions. The Executive Orders contained narrow exceptions for egregious misconduct (more specifically, for "acts or omissions that constitute a crime, fraud, malice, gross negligence, willful misconduct, or [that] otherwise constitute a false claim"). (Executive Orders 7U & 7V.)

[9] Citations to "RA" are to Dr. Rizvi's Appendix, which is attached. Citations to "CA" are to the Clerk's Appendix. Citations to "PA" are to Plaintiff's Appendix.

steps to conserve personal protective equipment ('PPE')" by, among other things, "minimizing in-person contact between patients and hospital personnel and limiting the number of[] personnel in contact with patients suspected of having COVID-19." (*See, e.g.*, *id.*)

More specifically, Hartford Healthcare modified many protocols to support the State's COVID-19 response and in light of, among other things, the potential shortage of PPE. For example and as most relevant here, Hartford Healthcare modified its protocols to "avoid administration of echocardiograms to patients who did not demonstrate an absolute clinical need [for them] and [to] avoid admitting patients who were suspected of having COVID-19 to Hartford Hospital's Cardiac Catheterization lab (the 'Cath Lab') until they had tested negative, unless their physical symptoms dictated the need for emergency catheterization." (*Id.* (emphasis added).)

These changes were not just driven by the fact that Hartford Healthcare was treating COVID-19 patients.[10] Hartford Healthcare was also evaluating patients to attempt to determine whether they had COVID-19 and thereby attempting to prevent COVID-19 from spreading to staff and non-COVID-19 patients, many of whom were elderly or otherwise at high risk. (*See, e.g.*, *id.*) Hartford Healthcare needed to use PPE and otherwise modify its protocols as described above (and in many other ways) to do all of that. (*See, e.g.*, *id.*)

Thus, Hartford Healthcare's response to the pandemic and provision of health care services in support of the State's COVID-19 response was multifaceted. Among other things, it not only treated COVID-19 patients, it also provided health care screening and diagnostic services to determine whether individuals had COVID-19.

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[10] Hartford Healthcare was treating COVID-19 patients throughout the time period in which it treated Ms. Mills. (*See, e.g.*, *id.*)

Hartford Healthcare's diagnostic services were a critical component of the State's COVID-19 response. As noted above, and as this Court has repeatedly recognized, the State's response centered on preventing and slowing the spread of the virus instead of letting everyone contract the virus and then trying to treat them. *See, e.g.*, *Casey*, 338 Conn. at 484. Diagnostic services were particularly important (and were not limited to giving people COVID-19 tests) during the early days of the pandemic because issues with the availability, processing time, and accuracy of COVID-19 tests during that time meant that health care workers could not rely on tests. Health care workers needed to use their training and experience to determine whether an individual likely had COVID-19 and should be isolated. Doing that was particularly critical to the State's containment and mitigation strategy when health care professionals were trying to determine whether a patient had COVID-19, which in certain cases did not require emergent care, or something else that required emergent care, because a determination that someone did not have COVID-19 when they really did would risk exposure to others.

C. Ms. Mills' Treatment

On March 21, 2020, Ms. Mills—Plaintiff's mother and a Registrar in the Emergency Room at Backus Hospital in Norwich—went to the Backus Emergency Room complaining of a "sore throat and [a] headache." (RA85–86.[11]) Ms. Mills noted that her granddaughter had recently had strep throat and informed staff that she had a heart murmur and needed a valve replacement (both longstanding conditions

[11] The Trial Court sealed some of Ms. Mills' medical records. Dr. Rizvi and Hartford Healthcare have not included such records in their Appendix, but have included other, unsealed medical records. The sealed records are referred to by their Exhibit number and letter.

for which Ms. Mills had previously declined (and continued to decline) treatment). Ms. Mills "denie[d] any chest pain" or shortness of breath. (*See, e.g.*, *id.*) Backus staff placed Ms. Mills on a cardiac monitor and obtained an EKG. (*See, e.g.*, *id.*)

Ms. Mills' EKG indicated "ST elevation." (*Id.*)

"ST elevation" *can* indicate a type of heart attack referred to as a "ST elevation myocardial infarction" (or "STEMI"). (*E.g.*, *id.*) It is undisputed that a patient suffering from a STEMI generally should receive emergency treatment in a Cardiac Catheterization Laboratory (a "Cath Lab") within a matter of hours, (*See, e.g.*, Pl. Br. 46.)

"ST elevation" can also, however, indicate far less serious conditions, including inflammation around the heart (conditions known as myocarditis and myopericarditis). (*See, e.g.*, RA67; RA71.) It is undisputed that such inflammation is *not* treated in a Cath Lab or even on an emergency basis. (*See, e.g.*, PA73.)

In other words, a STEMI cannot be diagnosed based on an EKG indication of "ST elevation" alone because such an indication can be indicative of other, non-emergency conditions. A STEMI is instead diagnosed based on overall symptoms and presentation. (*E.g.*, RA67.)

By the time of Ms. Mills' treatment, COVID-19 had been documented as causing inflammation around the heart. (*See, e.g.*, *id.*; RA70.) COVID-19 was therefore making it difficult to distinguish heart attacks from inflammation. (*See, e.g.*, RA70 ("COVID-19 patients were presenting with myocarditis simulating a STEMI presentation thus creating a novel diagnostic assessment. This was particularly true in patients like Ms. Mills presenting with sore throat and a headache and not chest pain and shortness of breath.").)

Hartford Healthcare's cardiologists, including Dr. Asad Rizvi, knew all of that prior to their treatment of Ms. Mills. (*E.g.*, RA67.)

Whether Ms. Mills' symptoms were caused by inflammation or a heart attack was therefore not clear. That was particularly true because (1) Ms. Mills' primary complaint of a sore throat and headache was consistent with a viral infection and thus inflammation, not a heart attack, and (2) because Ms. Mills denied having chest pain and other classic heart attack symptoms. (*See, e.g.*, RA67; RA70.)

In fact, Ms. Mills, who worked in an emergency room, did not believe she was having a heart attack when her Emergency Medicine doctor at Backus (Dr. Adams) suggested she might be. (RA86 ("She is . . . resistant to my concerns that she may be having an MI" (*i.e.*, a myocardial infarction (a heart attack)).)

Dr. Adams was nevertheless concerned enough that Ms. Mills might have been having a heart attack that she called Hartford Hospital and spoke to Dr. Rizvi, the Interventional Cardiologist on call in Hartford Hospital's Cath Lab.[12] (*Id.*) Dr. Adams described Ms. Mills' presentation to Dr. Rizvi. (*Id.*)

Dr. Rizvi was immediately concerned that Ms. Mills might have been infected with COVID-19 (or another viral infection) causing inflammation instead of having a heart attack. (*See, e.g.*, *id.*) Dr. Rizvi's concern was based in part on the fact that Dr. Adams had told Dr. Rizvi that Ms. Mills had a sore throat and headache, symptoms consistent with a viral infection, not a heart attack. (*E.g.*, *id.*)

Hartford Healthcare's COVID-19 protocols required Dr. Rizvi to determine whether Ms. Mills was more likely infected with COVID-19 or having a heart attack because, as noted above, the latter required treatment in the Cath Lab, but the former did not and Dr. Rizvi could not send Ms. Mills to the Cath Lab under Hartford Healthcare's COVID-19 protocols if he suspected she was suffering from COVID-19 instead of having a heart attack. (*See, e.g.*, RA63; RA67.) Dr. Rizvi

[12] Backus did not have a Cath Lab.

therefore recommended that Ms. Mills be transferred from Backus to Hartford Hospital so that he could evaluate her.[13] (RA87; *see also, e.g.*, RA68 (noting that Dr. Rizvi's decisions were made "in light of [Hartford Healthcare's] infectious disease policies").)

When Ms. Mills arrived at Hartford Healthcare, Dr. Rizvi donned full PPE and examined her to try to determine whether she was in fact having a heart attack or was suffering from COVID-19, as required in order to determine whether Ms. Mills could go to the Cath Lab under Hartford Healthcare's COVID-19 protocols. (*E.g.*, RA102.)

Whatever opinion Dr. Rizvi rendered would determine whether Ms. Mills could go to the Cath Lab. If he felt her presentation was more consistent with a heart attack, she could go the Cath Lab immediately. (*See, e.g.*, RA63.) Conversely, if he felt her presentation was more consistent with viral inflammation potentially caused by COVID-19, Ms. Mills could not go to the Cath Lab. (*See, e.g.*, *id.*)

During Dr. Rizvi's examination, Ms. Mills again complained of a sore throat and headache and continued to deny chest pain or shortness of breath. (Ex. 1.B.) Ms. Mills told Dr. Rizvi she worked "in the emergency room at Backus" and was "unsure if she ha[d] been exposed to potential patients with viral symptoms recently." (Ex. 1.B.)

> [Based on all the circumstances,] including, but not limited to, Ms. Mills' high risk for exposure to COVID-19 based on her employment as a registrar in the Backus ED, the nature and duration of symptoms upon

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[13] Dr. Rizvi did not, however, recommend that Ms. Mills be transferred directly to Hartford Hospital's Cath Lab. (RA102.) Dr. Rizvi could not have recommended that because it would have been a violation of Hartford Healthcare's COVID-19 protocols in light of Dr. Rizvi's belief that Ms. Mills was suffering from non-life threatening inflammation possibly caused by COVID-19. (*See, e.g.*, RA63.)

> presentation which were consistent with a viral infection, and the notable absence of cardiac symptoms upon presentation, [Dr. Rizvi] believed, based on [his] medical training and experience, that Ms. Mills could be experiencing a cardiac inflammatory condition . . . secondary to a viral syndrome, and that this viral syndrome was possibly COVID-19.

(RA67; *see also, e.g.*, RA91 (noting that Dr. Rizvi's impression was "[v]iral syndrome with myopericarditis" (*i.e.*, inflammation) "[v]ery low suspicion for . . . STEMI").)

In other words, Dr. Rizvi believed that Ms. Mills more likely had viral inflammation. (*Id.*) Dr. Rizvi therefore could not and did not send Ms. Mills to the Cath Lab "in light of [Hartford Healthcare's] infectious disease policies" (*i.e.*, its COVID-19 policies). (*See, e.g.*, RA63; RA68.) Dr. Rizvi therefore created a treatment plan for Ms. Mills that, as dictated by Hartford Healthcare's COVID-19 protocols, called for Ms. Mills to remain on cardiac monitoring and in isolation pending the administration and receipt of a COVID-19 test, which Dr. Rizvi ordered, after which Ms. Mills would obtain a non-emergency consultation in the Cath Lab. (RA91 ("[P]lace patient in isolation and rule out infection etiology including COVID-19."); Ex. 1.B ("[D]efer cath until infectious issues are cleared.").) Other doctors followed that plan.

Dr. Rizvi's opinion was directly and significantly affected by the pandemic. For example, COVID-19 was making it difficult to distinguish heart inflammation from heart attacks. (*See, e.g.*, RA70.) Hartford Healthcare's polices nevertheless required Dr. Rizvi to determine which of those conditions Ms. Mills was more likely suffering from, which is what Dr. Rizvi did. (*See, e.g.*, RA67–68.) Dr. Rizvi's decision was informed, in significant part, by the fact that Ms. Mills was at a high risk for exposure to COVID-19 and was exhibiting

symptoms consistent with a viral infection and inconsistent with a heart attack (because of the absence of, *e.g.*, chest pain). (*Id.*)

The pandemic continued to directly and significantly impact Ms. Mills' care. (*See, e.g.*, RA102.) For example, Defendant Dr. Ferraro-Borgida "did not enter [Ms. Mills'] room," forewent a physical examination, and instead spoke to Ms. Mills by phone "in the interest of *preserving scarce resources* (PPE) and *limiting unnecessary exposures* to avoid workforce shortages."[14] (*Id.* (emphasis added).)

Ms. Mills' condition remained stable and she continued to deny chest pain over the next few days.[15] (*See, e.g.*, RA96 ("[S]he is hemodynamically stable. She is asymptomatic with no signs of heart failure or ongoing chest pain. . . . Patient denies any dyspnea or chest pressure."); RA106 ("She remains chest pain free as she has been all along. . . . Her *only* symptoms have been sore throat with difficulty swallowing and headache and toothache." (Emphasis added)).)

Ms. Mills' COVID-19 test came back late on March 24, 2020 (even though it was administered on March 21, 2020, when Ms. Mills first arrived at Hartford Hospital). (RA93.) Ms. Mills was scheduled to go to the Cath Lab the following morning (March 25, 2020). (RA71.)

Tragically, however, Ms. Mills went into cardiac arrest and passed away early on the morning of March 25, 2020. (RA95.)

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[14] As another example, only a "limited number of images were obtained" of Ms. Mills' heart because she was "a suspected . . . COVID-19 patient." (*See, e.g.*, RA105.)

[15] Ms. Mills also rebuffed doctors' attempts to talk to her about and treat the long-existing heart valve issues for which Ms. Mills had previously declined treatment. (*E.g.*, RA99 ("[Patient] is not willing to stay for bypass surgery or any type of valve intervention[.]").)

3. PROCEDURAL HISTORY

Plaintiff then filed this wrongful death/medical malpractice action against Hartford Healthcare and four cardiologists who treated Ms. Mills: Drs. Rizvi, Ferraro-Borgida, Duncan, and Farrell (collectively with Hartford Healthcare, the "Defendants"). Plaintiff asserts the Defendants were negligent and grossly negligent. (CA9.)

The Defendants moved to dismiss Plaintiff's Complaint on the ground that they were immune from suit under Executive Order 7V and the PREP Act. (*E.g.*, CA38–39.) The Trial Court granted the Defendants' Motions in relevant part.[16] It held that immunity existed under both Executive Order 7V and the PREP Act.

> With respect to Executive Order 7V, the Court explained: [T]he [D]efendants were providing health care services in support of the [S]tate's response to the pandemic because . . . the defendants' had a good faith belief that they may be treating an actual COVID-19 patient. Dr. Rizvi averred that he was aware that viral infections could cause abnormal cardiac readings and that he was

[16] The Trial Court granted the Defendants' Motions as to "acts or omissions prior to 7:40 p.m. on March 24, 2020," when Ms. Mills' COVID-19 test came back negative, but cut off immunity after that time. (CA53.) That cut off only affected Dr. Farrell and Hartford Healthcare (all other Defendants were dismissed from the case entirely). Dr. Farrell and Hartford Healthcare challenge the Trial Court's cut off in separate appeals. (S.C. 20763 & S.C. 20764.) As the propriety of the Trial Court's cut off is being briefed in those appeals, Dr. Rizvi and Hartford Healthcare do not discuss that issue here. For the reasons in its brief(s) in its appeal, Hartford Healthcare maintains, however, that the Trial Court should not have cut off immunity.

> concerned that COVID-19 was the very vir[al] infection causing Ms. Mills' abnormal readings. Moreover, Ms. Mills could not say that she was not exposed to COVID-19 at her job registering patients at Backus Hospital's ER and it was an entirely reasonable concern on the part of Dr. Rizvi and the defendants that Ms. Mills may have been exposed to COVID-19 in that role. Similarly, it was a reasonable concern on the part of Dr. Rizvi and the defendants that Ms. Mills' granddaughter's respiratory virus may have been a missed case of COVID-19, particularly in the early days of the pandemic when comparatively little was known about COVID-19. . . . Finally, the [C]ourt concludes that the circumstances of this case are plainly anticipated by Executive Order 7V because Ms. Mills' delayed transfer to the cardiac catheterization lab was directly tied to Hartford Hospital's attempt to conserve scarce PPE.

(CA50.)

> With respect to the PREP Act, the Trial Court explained: [T]he [C]ourt concludes that the PREP Act provides immunity . . . because [Plaintiff's] claims plainly are related to, and arise out of, a COVID-19 diagnostic counter measure, specifically, Ms. Mills' COVID-19 test. The gravamen of the [Plaintiff's] claim is that the [D]efendants[] delayed Ms. Mills care for a heart attack because the [D]efendants' mistakenly thought Ms. Mills had COVID-19. The reason why the [D]efendants' thought Ms. Mills had COVID-19 from March 21st to March 24th arose out of and was related to the fact that

they were awaiting the results of a COVID-19 diagnostic test, a "covered countermeasure" under the PREP Act. (CA52.)

This appeal followed.[17]

4. ARGUMENT

A. Standard of Review

The standard of review for all issues in this appeal is *de novo*,[18] except that the Trial Court's factual findings "are binding upon this [C]ourt unless they are clearly erroneous." *McKay v. Longman*, 332 Conn. 394, 417, 211 A.3d 20, 38 (2019). "A finding of fact is clearly erroneous when there is no evidence . . . to support it or when although there is evidence to support it, the . . . [C]ourt . . . is left with the definite and firm conviction that a mistake has been committed." *Id.*

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[17] There were subsequent proceedings in the Trial Court (regarding how the Trial Court's decision applied to each Defendant) and the Appellate Court (regarding procedural issues). (*See, e.g.*, CA54–80 & Appellate Court Docket.) Those proceedings are largely irrelevant here but are discussed below to the extent they are relevant.

[18] *See, e.g.*, *Gagliano v. Advanced Specialty Care, P.C.*, 329 Conn. 745, 767, 189 A.3d 587, 600 (2018) (questions of law subject to *de novo* review); *Seramonte Assocs., LLC v. Town of Hamden*, 345 Conn. 76, 83, 282 A.3d 1253, 1257 (2022) (statutory interpretation subject to plenary review); *see also, e.g.*, *Sena v. Am. Med. Response of Connecticut, Inc.*, 333 Conn. 30, 54, 213 A.3d 1110, 1125 (2019) (construction of immunity subject to plenary review); *Fay*, 338 Conn. at 25 (applying rules for challenges to statutes to challenge to Executive Order).

The Parties agree that this Court should discern and effectuate Governor Lamont's intent when he promulgated the Executive Orders in determining the scope of immunity under those Orders. (Pl. Br. 23.)

"When construing a[n] [Executive Order], [this Court's] fundamental objective is to ascertain and give effect to the apparent intent of the [Governor]." *Seramonte Assocs., LLC v. Town of Hamden*, 345 Conn. 76, 83, 282 A.3d 1253, 1257 (2022) (quotation marks omitted). "In other words, [this Court] seek[s] to determine, in a reasoned manner, the meaning of the [executive] language as applied to the facts of the case . . . ." *Id.* (quotation marks omitted).

B. Immunity Exists Under The Standard Plaintiff Proffers For Immunity

Plaintiff concedes that immunity exists where "defendants were following protocols that had been altered in good faith as part of Hartford Hospital's COVID-19 response." (Pl. Br. 43.)

That standard is met in this case numerous times over.

First and foremost, it is undisputed that Hartford Healthcare "modified its protocols to, among other things, . . . avoid admitting patients who were suspected of having COVID-19 to [the Cath Lab] until they had tested negative, unless their physical symptoms dictated the need for emergency catheterization" as part of its COVID-19 response (RA63.) That protocol required Dr. Rizvi to determine whether Ms. Mills was more likely having a heart attack or suffering inflammation caused by COVID-19 (or another virus). Dr. Rizvi adhered to Hartford Healthcare's COVID-19 protocols by doing exactly that. (RA68 ("I determined . . . that the most prudent course of action *in light of the infectious disease protocols at that time given the COVID-19 treatment environment* was to delay Ms. Mills's admission to the Cath Lab pending receipt of the results of a COVID-19 test . . . .")

(emphasis added); *see also, e.g.*, RA91 ("Viral syndrome with [inflammation]. Very low suspicion for [a heart attack].").)

Second, it is also undisputed that Hartford Healthcare modified its protocols "to conserve [PPE]" and that those modifications included "minimizing in-person contact between patients and hospital personnel and limiting the number of hospital personnel in contact with patients suspected of having COVID-19." (RA63.) The defendants followed that protocol, which affected Ms. Mills' treatment. Dr. Ferraro-Borgida, for example, "did not enter [Ms. Mills'] room," did not conduct a physical examination of Ms. Mills, and instead spoke to Ms. Mills by phone "in the interest of *preserving scarce resources* (PPE) and *limiting unnecessary exposures* to avoid workforce shortages."[19] (RA102 (emphasis added).)

Plaintiff's contention that "the protocols for diagnosing and treating a non-COVID-19 condition dictated business as usual" is flat out wrong. Hartford Healthcare's COVID-19 protocols precluded Dr. Rizvi from sending Ms. Mills to the Cath Lab until he made a decision regarding whether Ms. Mills more likely had non-life threatening inflammation caused by COVID-19 or was having a heart attack.

If Hartford Healthcare's COVID-19 protocols were not in place, Ms. Mills would have gone to the Cath Lab right away because, even after his evaluation, Dr. Rizvi still concluded that Ms. Mills should go to the Cath Lab (on a non-emergency basis). (*See, e.g.*, RA68.[20])

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[19] The Executive Orders provide for immunity where, as here, a claim concerns "acts or omissions undertaken because of a lack of resources[] attributable to the COVID-19 pandemic." (Executive Orders.)

[20] *See also, e.g.*, RA107 ("Waiting for COVID testing to become negative but do suggest cardiac catheterization before hospital discharge.");

In sum, Hartford Healthcare's COVID-19 protocols required Dr. Rizvi to determine whether Ms. Mills was more likely having a heart attack or inflammation and then precluded Dr. Rizvi from sending Ms. Mills to the Cath Lab because of his determination. Hartford Healthcare's COVID-19 protocols then continued to directly affect Ms. Mills' care, including by causing Dr. Ferraro-Borgida to forego a physical examination of Ms. Mills. Immunity exists under Plaintiff's own standard because Plaintiff concedes that immunity exists where defendants "follow[] protocols . . . altered in good faith . . . as part of [the State's and/or provider's] COVID-19 response."[21] (Pl. Br. 43.)

C. The Defendants Were Providing Health Care Services In Support Of The State's Response

Plaintiff fundamentally misunderstands the plain language of "health care services in support of the State's COVID-19 response."

As this Court has recognized and as discussed above, the State's primary response to COVID-19 was containment and prevention (*i.e.*, Governor Lamont's plan was to try to limit the spread of the virus rather than to let everyone get the virus and then try to treat everyone). *See, e.g.*, *Casey*, 338 Conn. at 484.

RA96 ("Once she is ruled out for Covid 19 infection she will undergo a right and left heart cath.").

[21] Plaintiff's focus on the fact that Dr. Rivzi could have sent Ms. Mills to the Cath Lab immediately *if* he determined she was having a heart attack is a distraction. That ability did not exist under the facts of this case, where Dr. Rizvi concluded Ms. Mills more likely had heart inflammation. As discussed above and below, Dr. Rizvi's decision was required and substantially affected by COVID-19, which among other things made it difficult to distinguish inflammation from heart attacks.

A core component of the State's health care response to COVID-19 was therefore to identify and isolate individuals who may have or likely had COVID-19.[22] That was particularly true during March 2020, when Hartford Healthcare and its doctors treated Ms. Mills. At that time, tests took days and were faulty. *See, e.g.*, *Fay*, 336 Conn. at 437 n.7. Health care providers could not administer a test and reliably know whether the patient had COVID-19. They had to determine that based on symptomology and their medical expertise.

Trying to determine whether a patient had COVID-19 so that the patient could be appropriately treated (and isolated) was therefore a "health care service[] in support of the State's COVID-19 response." In fact, given the importance of containment and isolation, diagnostic assessments of patients to try to determine if they had COVID-19 was one of the most important health care services to the State's response.

The Defendants were trying to determine whether Ms. Mills had COVID-19 or was suffering from a heart attack. (*See, e.g.*, RA67.) They were trying to do so not only so that they could properly treat Ms. Mills, but also so that they could determine whether or not they could send Ms. Mills to the Cath Lab, which would have required vital PPE and risked exposure to COVID-19. They were therefore providing "health care services in support of the State's COVID-19 response" and have immunity under the plain language of the Executive Orders.

To understand how important the diagnostic assessment Dr. Rizvi performed was to the State's response to COVID-19, one need only consider what would have happened if doctors let patients with viral symptoms and a high risk of exposure to COVID-19 (like Ms. Mills) go for treatment without screening them to determine whether

[22] A core component of the State's health care response was also to preserve PPE and, as just noted, Governor Lamont provided immunity for decisions related to the preservation of PPE. (Executive Orders.)

they actually needed that treatment or whether they had COVID-19. Patients with COVID-19 would invariably have been sent for treatment they did not need, thereby unnecessarily exposing staff and thus other patients to the virus, which would have fueled the pandemic and undermined the State's containment policy.

The Trial Court correctly recognized that the Defendants were providing health care services by holding that the Defendants had immunity "because . . . [they] had a good faith belief that they may [have been] treating an actual COVID-19 patient." (CA49.)

D. Plaintiff's Attempt To Distinguish Confirmed From Suspected COVID-19 Patients Fails

Plaintiff concedes that immunity would "certainly" apply if the Defendants "were actually treating COVID-19," (Pl. Br. 43), but contends that the Defendants do not have immunity for treating Ms. Mills, a suspected COVID-19 patient, (*see, e.g.*, RA105 ("This is a . . . study for a suspected or confirmed COVID-19 patient.")

Plaintiff's attempt to distinguish treatment of confirmed COVID-19 patients from treatment of suspected COVID-19 patients is inconsistent with the plain language of the Executive Orders and makes no sense. As just discussed, determining whether a patient might have COVID-19 and determining whether they actually needed treatment that would have required the use of precious PPE[23] and risk exposure (both to the patient and from the patient to others) was a "health care service[] in support of the State's COVID-19 response."

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[23] As noted above, Hartford Healthcare was not just using PPE with suspected or confirmed COVID-19 patients. It was using it generally to prevent patients and staff from getting COVID-19 and in accordance with health guidance that assumed that many people had COVID-19.

Distinguishing suspected from confirmed cases is also inconsistent with the State's policy of containment, which relied on health care workers being able to make decisions with respect to individuals who they believed in good faith might have COVID-19 even though workers had not confirmed or could not confirm that.

Moreover, as this Court has recognized, experts advised "that people with mild symptoms consistent with COVID-19 be assumed to be infected with the disease," *Fay*, 336 Conn. at 436 n.7, and Governor Lamont adopted those recommendations, *see, e.g.*, footnote 1; Executive Order 7QQ. In other words, in accordance with public health guidance, Governor Lamont instructed that suspected or potential COVID-19 patients should be considered COVID-19 patients.

It therefore makes no sense to distinguish between suspected COVID-19 patients and confirmed COVID-19 patients for purposes of Governor Lamont's Executive Orders 7U & 7V. Governor Lamont certainly did not intend immunity to turn on whether a suspected COVID-19 patient turned out to actually have COVID-19.[24] Such immunity would be useless and would undermine Governor Lamont's goals of increasing the health care workforce and encouraging doctors to take whatever actions were needed by rendering health care workers immune to suit because of their good faith actions to combat the pandemic. This case presents an excellent example. Doctors made decisions because of well-founded concerns that Ms. Mills had COVID-

[24] As noted above, Plaintiff concedes that this Court's objective is to ascertain and give effect to Governor Lamont's intent. (*See, e.g.*, Pl. Br. 20.) As explained in more detail in Hartford Healthcare's Brief in its appeal, Governor Lamont intended immunity to be broad because broad immunity was needed to effectuate his primary goals of growing the State's health care workforce and encouraging health care workers to do what was necessary to combat the pandemic.

19. Ms. Mills ended up not having COVID-19,[25] and Plaintiff therefore says Defendants can be sued (or, alternatively, that they can be sued because doctors had not confirmed (and could not confirm) whether Ms. Mills had COVID-19 during their initial evaluations of Ms. Mills).

E. COVID-19 Affected Ms. Mills' Diagnosis

Plaintiff's assertion that Dr. Rizvi's (and the other Defendants') assessments of Ms. Mills were unaffected by COVID-19 is incorrect.

It is undisputed and indisputable that COVID-19 infections were simulating heart attacks. (*See, e.g.*, RA70 ("[P]atients were presenting with suspected COVID-19 related myocarditis simulating an ST Elevation Myocardial Infarction ('STEMI'), thus creating novel diagnostic and therapeutic challenges for patient assessment . . . .").

It is undisputed and indisputable that the novel diagnostic and therapeutic challenges created by COVID-19 were particularly acute in cases like Ms. Mills' case, where the patient did not complain of traditional heart attack symptoms and their primary complaint was consistent with a viral infection. (*See, e.g.*, *id.* ("COVID-19 patients were presenting with myocarditis simulating a STEMI presentation thus creating a novel diagnostic assessment. This was particularly true in patients like Ms. Mills presenting with sore throat and a headache and not chest pain and shortness of breath.").)

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[25] Under Governor Lamont's view and in light of issues with early COVID-19 tests, however, doctors should still have assumed that Ms. Mills might have had COVID-19. *See, e.g.*, *Fay*, 336 Conn. at 436 n.7 (quoting Governor Lamont). That makes Plaintiff's attempt to distinguish confirmed COVID-19 patients from suspected COVID-19 patients even more at odds with Governor Lamont's intent.

It is undisputed and indisputable that Ms. Mills' case was even more vexing because she worked in an emergency room and was therefore at an exceptionally high risk for COVID-19. (RA67.)

It is undisputed and indisputable that the requirement that Dr. Rizvi determine what Ms. Mills was more likely afflicted with was due to COVID-19 (more specifically, a COVID-19 policy). (RA63.)

Plaintiff's contention that health care workers were ignoring all of that and deciding whether someone had a heart attack under a pre-COVID-19 "business as usual" approach is wrong. (Pl. Br. 36 & 43.)

Plaintiff's attempt to evade immunity by presenting this case (with the benefit of hindsight) as an obvious heart attack case is also inconsistent with these and other undisputed facts (such as the fact that Ms. Mills, who worked in an emergency room, did not believe she was having a heart attack (*see, e.g.*, RA86)).

Regardless, Plaintiff's position that immunity turns on whether health care workers were right or wrong is not correct. Governor Lamont did not intend for immunity to turn on that because such immunity would be useless and do nothing to increase the State's health care workforce or encourage health care workers to engage in acts necessary to combat the pandemic they otherwise would not have.

F. The Executive Orders Are Well Within Constitutional Limits

The Executive Orders do not come close to infringing upon any Constitutional limits imposed on Governor Lamont's discretion. That is true under even the broadest scope of immunity advocated here.

The Governor's authority to promulgate pandemic related executive orders is statutory. *See, e.g.*, Conn. Gen. Stat. § 28-9; *see also, e.g.*, *Casey*, 338 Conn. at 492 (upholding Constitutionality of § 28-9). This Court has recognized "that the General Assembly instructed [Governor Lamont] to exercise the powers delegated to him [by statute]

broadly for 'the protection of the public health'; General Statutes § 28-9(b)(1); and 'to protect the health, safety and welfare of the people of the state . . . .' General Statutes § 28-9(b)(7)." *Id.* "A narrow interpretation of the circumstances under which the governor would have authority to proclaim a civil preparedness emergency . . . would frustrate this legislative intent." *Id.* at 492–93 (emphasis added); *e.g.*, *id.* at 518 (noting that § 28-9 "represents a broad grant of authority").

As relevant here, the legislature vested in Governor Lamont the authority to (1) "modify or suspend in whole or in part . . . any statute . . . or requirement or part thereof *whenever* the Governor finds such statute . . . or part thereof . . . is in conflict with the efficient and expeditious execution of civil preparedness functions or the protection of the public health," Conn. Gen. Stat. § 28-9(b)(1), and (2) "take such other steps as are reasonably necessary in the light of the emergency to protect the health, safety and welfare of the people of the state," Conn. Gen. Stat. § 28-9(b)(7). This Court has held that the latter provision authorized Governor Lamont to close and otherwise restrict the functioning of bars and restaurants because of the pandemic. *Casey*, 338 Conn. at 523. This Court has also explained that actions that Governor Lamont would *not* be able to take under § 28-9(b)(7) are actions that plainly have nothing to do with the emergency at issue (for example, requiring masks due to a hurricane). *Id.* at 508–09.

Governor Lamont enacted Executive Orders 7U & 7V in large part to expand the State's health care workforce and encourage health care workers to perform acts they would not ordinarily perform. (*See* Executive Orders.) Expanding the health care workforce and encouraging health care workers to do whatever was needed to combat the pandemic was unquestionably reasonably necessary to combat the

pandemic.[26] More health care workers would be needed because there was about to be a massive increase in patients combined with a decrease in health care workers when certain workers invariably contracted the virus. *See, e.g.*, *Casey*, 338 Conn. at 482 (noting that the pandemic caused "many hospitals and other health-care operations [to be] overrun by gravely ill and dying patients"). The increased demand for health care services, decreased availability of such services, and need to limit exposure made it at least reasonably necessary (if not imperative) to encourage health care workers to, for example, perform acts outside of their routine duties or even their specialties.

At minimum, given that closing and otherwise imposing restrictions on bars and restaurants was reasonably necessary to combat the pandemic, taking action to increase the health care workforce and encourage workers to do what was necessary was also reasonably necessary to help combat the pandemic.[27]

Moreover, there is no Constitutional issue under the facts of this case. As noted above, § 28-9(b)(1) allows Governor Lamont to suspend statutes if he finds them to be in conflict with the protection of public health. That authority is separate from and in addition to Governor Lamont's authority to do whatever is "reasonably necessary" under § 28-9(b)(7). "[N]o action for wrongful death existed at common law or exists today in Connecticut except as otherwise provided by the

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[26] Plaintiff does not challenge the means by which Governor Lamont acted to achieve those goals (immunity). That is wise because "it is not the job of this [C]ourt to second-guess [the Governor's] policy decisions," including how Governor Lamont achieves objectives reasonably related or necessary to combat an emergency so "long as [the Governor] is acting within his . . . broad . . . authority." *Id.* at 523.

[27] The Trial Court held as much. (*See* CA51.)

legislature." *Ecker v. Town of W. Hartford*, 205 Conn. 219, 231, 530 A.2d 1056, 1062 (1987). Under the plain language of § 28-9(b)(1), Governor Lamont could have precluded wrongful death actions that arose during the underlying time period if he found them to be in conflict with the efficient response to the pandemic.[28]

Besides a theoretical dispute about what Governor Lamont could have done, Plaintiff does not dispute any of this. Instead, she asserts that immunity would be un-Constitutional here because, according to her, the acts at issue here "are not related to the COVID-19 pandemic." (*See, e.g.*, Pl. Br. 29.) Taking a patient who may have COVID-19 aside to determine whether she has COVID-19 and/or whether she actually needs certain treatment that will require the use of PPE and risk exposure to COVID-19 is clearly related to the pandemic. Ms. Mills' treatment was inextricably intertwined with the pandemic for all the other reasons discussed above and below.

Plaintiff also attempts to distract this Court with inapplicable examples concerning individuals who were in obvious mortal danger (such as someone suffering a life-threatening gunshot wound). Those examples ignore the fact that the Defendants had good faith questions about what Ms. Mills, whose principal complaint was a sore throat and headache, was suffering from or whether she was suffering from

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[28] Dr. Rizvi and Hartford Healthcare do not contend that Governor Lamont did that. The point is that (1) Governor Lamont could have done it (within Constitutional limits) given that this Court has upheld the Constitutionality of § 28-9, that (2) Governor Lamont could have found that the threat of a massive wave of wrongful death suits during a pandemic would lead doctors to, among other things, waste PPE and risk exposure practicing "defensive medicine," and (3) that what Governor Lamont actually did in Executive Orders 7U & 7V is thus well within Constitutional bounds and his authority under § 28-9.

anything life-threatening at all. This case is not comparable to a case involving someone shot in the chest, an obvious life-threatening injury.

More generally, Plaintiff attempts to invoke fears that applying immunity here would lead to immunity in all sorts of cases. But immunity here is no stretch. Doctors had a good faith belief that a patient complaining principally of a sore throat and a headache had COVID-19 and doubted she was having a heart attack. That good faith belief regarding COVID-19 immediately, substantially, and irreversibly altered the patient's treatment. This is a prototypical case for immunity, not a case on the outer limits of immunity. Whatever the outer limits of immunity are, they are not tested here.

G. The PREP Act Provides Immunity

As relevant here, the PREP Act provides extremely broad immunity for *activities* related to the administration of COVID-19 tests and other "covered countermeasures" and *decisions* to administer COVID-19 tests.[29] *E.g.*, Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (March 17, 2020) ("Declaration").

Put differently, the PREP Act does *not just* provide immunity for injuries caused by or related to the administration of a COVID-19 test (*e.g.*, a contaminated test swab that causes an infection).[30] The PREP

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[29] Plaintiff admits that Ms. Mills' COVID-19 test was a covered countermeasure, (Pl. Br. 45), and does not dispute that the Defendants are "covered person[s]" under the PREP Act, (Pl. Br. 44–48).

[30] As set forth in footnote 22 of Hartford Healthcare's principal Brief in its appeal (S.C. 20764), courts disagree as to whether the PREP Act provides immunity for all claims for "injuries 'arising out of, relating to, or resulting from' the[] administration or use" of "covered

Act also provides immunity for injuries caused by or related to the decision to administer a COVID-19 test (*e.g.*, the decision to administer a test causes a delay in other treatment that allegedly causes injury).

The Secretary of the Department of Health and Human Services made that clear in his COVID-19 PREP Act Declaration by defining the "administration of covered countermeasures" to include "*activities and decisions* directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients[and] management and operation of countermeasure programs." Declaration, 85 Fed. Reg. 15,200 (emphasis added).

The Secretary's Declaration also included examples to make that clear, including a hypothetical where an individual was injured "at a retail store serving as an administration or dispensing location" based, allegedly, on "lax security or chaotic crowd control." *Id.* In that situation, the "covered countermeasures" the store was dispensing did not "cause" injury. Lax security allegedly did. Yet immunity would still apply because the injury was related to the administration of a "covered countermeasure." *See, e.g.*, *id.*; *see also, e.g.*, *Storment v. Walgreen, Co.*, No. 1:21-CV-00898 MIS/CG, 2022 WL 2966607 (D.N.M. July 27, 2022) (holding that immunity applied to an alleged slip-and-fall outside of a Walgreens after the plaintiff received a COVID-19 vaccination because the plaintiff's alleged injury could not "be divorced from the administration of a covered countermeasure").

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countermeasures," or all claims that have a causal relationship with "the administration or use" of a "covered countermeasure." This Court need not resolve that dispute because either test is satisfied here. The broader "related to" view is, however, more consistent with the broad scope of immunity intended by the PREP Act.

The Department of Health and Human Services subsequently issued an Advisory Opinion (that now has the force of law[31]) illustrating the breadth of immunity. (HHA78.) The Department noted that a court "was wrong" when it held that "PREP Act immunity . . . 'only applies to the actual use of the [covered countermeasure].'" The Department explained that "'administration' is *broader than the 'physical provision of a countermeasure*.'" (*Id.* (emphasis added).)

Consistent with those decisions, the Court in *Storment*, 2022 WL 2966607, at *3, held that PREP Act immunity applied to a "chain of events" that could not "be divorced from the administration of a covered countermeasure—the COVID-19 vaccine." The plaintiff in that case "went to Walgreens for her COVID-19 vaccination, received such vaccination[,] but then had no chairs to sit on for monitoring immediately following inoculation." *Id.* "Thus, she ultimately went to the parking lot to sit in her car but became dizzy and fell before she could get seated." *Id.* "She fell [] and fractured her elbow[.]" *Id.*

The PREP Act likewise provides immunity in this case because Plaintiff's claim is inextricably intertwined with the decision to administer a COVID-19 test. As the Trial Court correctly explained:

> The gravamen of [Plaintiff's] claim is that the [D]efendants' delayed Ms. Mills' care for a heart attack because the [D]efendants[] mistakenly thought Ms. Mills had COVID-19. The reason why the [D]efendants[] thought Ms. Mills had COVID-19 from March 21st to March 24th arose out of and was related to the fact that

[31] After he issued the Advisory Opinion, the Secretary incorporated it into his Fourth Amended Declaration under the PREP Act and stipulated "that the Declaration must be construed in accordance with the . . . Advisory Opinions." 85 Fed. Reg. 79191.

they were awaiting the results of a COVID-19 diagnostic test, a "covered countermeasure" under the PREP Act.

(CA52.) Put differently, and as was the case in *Storment*, 2022 WL 2966607, at *3, Plaintiff's claim involves a series of events that cannot "be divorced from the administration of a covered countermeasure." Dr. Rizvi believed that Ms. Mills was more likely experiencing inflammation caused by a viral infection (COVID-19) than a heart attack. Dr. Rizvi decided to administer a COVID-19 test as part of that decision (which, as noted above, was affected by COVID-19 and made in accordance with Hartford Healthcare's protocols).[32] Because Plaintiff's claim is that Dr. Rizvi "misdiagnosed" Plaintiff as more likely having COVID-19 than a heart attack, Plaintiff's claim cannot be divorced from Dr. Rizvi's decision to administer a COVID-19 test. Plaintiff's argument to the contrary asserts that Dr. Rizvi's decision somehow had nothing to do with COVID-19 even though the undisputed facts establish otherwise (as previously discussed).

In sum, the PREP Act applies to the decision to administer a COVID-19 test. Because Plaintiff's claim is part and parcel with that decision because it is based on the diagnosis regarding whether Ms. Mills more likely had COVID-19 and thus needed a COVID-19 test, the Defendants are entitled to immunity under the PREP Act.[33]

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[32] Put differently, Dr. Rizvi ordered a COVID-19 test because he thought Ms. Mills was more likely infected by COVID-19 than having a heart attack.

[33] Plaintiff's arguments on this point are also at odds with the broad scope of immunity under the PREP Act. Her view effectively destroys the Act's extension of immunity to decisions regarding covered countermeasures by attempting to re-characterize directly related decisions as something having nothing to do with countermeasures.

H. Plaintiff's "Gross Negligence" Claims Fail

1. The PREP Act Precludes These Claims

Plaintiff's "gross negligence" claims fail because the PREP Act applies for the reasons set forth above and the PREP Act does not include an exception for "gross negligence" claims. 42 U.S.C. § 247d-6d(c) (noting "negligence in any form" cannot overcome immunity).

2. Plaintiff Cannot Satisfy The High Threshold For "Gross Negligence"

Even if the PREP Act did not preclude "gross negligence" claims, the facts of this case do not come close to satisfying the "high threshold of egregiousness necessary" for "gross negligence." *Boone v. William W. Backus Hosp.*, 272 Conn. 551, 567–68, 864 A.2d 1, 14 (2005).

In the medical malpractice context, "gross negligence" occurs where "a lay jury could conclude, on the basis of its own common knowledge, that the defendant's conduct constituted an obvious and egregious violation of an established standard of care and that this violation proximately caused the decedent's injuries and death." *Id.*

An example of "gross negligence" is leaving foreign objects in a surgery patient's body. *Id.* at 567. Conversely, "gross negligence" is *not something like an alleged failure to associate symptoms with one medical condition as opposed to another*, such as allegedly concluding that symptoms "were consistent with an uncomfortable but nevertheless normal reaction to [] medication [] instead [] of a serious allergic reaction requiring readmission and treatment." *Id.* at 570.

Outside the medical malpractice context, this Court has "defined gross negligence as very great or excessive negligence, or as the want of, or the failure to exercise, even slight or scant care or slight diligence" and as requiring "*more than* momentary thoughtlessness, inadvertence or *error or judgment*" and something such as "aggravated

disregard for the rights and safety of others." *Riccio v. Bristol Hosp., Inc.*, 341 Conn. 772, 784, 267 A.3d 799, 806 (2022) (emphasis added).

The undisputed facts of this case do not come close to satisfying the "high threshold of egregiousness necessary" for "gross negligence."

A lay person does not know how to interpret an EKG, what a STEMI is, what myocarditis and myopericarditis are, how one might distinguish a STEMI from myocarditis or myopericarditis, or what a Cath Lab is or what happens there. A jury could not conclude that it was malpractice not to send a patient complaining principally of a sore throat and a headache to a Cath Lab based on common knowledge.[34]

This case is analogous to *Boone*, where this Court held that the failure to properly diagnose the cause of certain symptoms was not "gross negligence." *Boone*, 272 Conn. at 570. Plaintiff argues that this is a "misdiagnosis" case (*i.e.*, that doctors failed to properly diagnose Ms. Mills' symptoms). (Pl. Br.) This case is not anything like leaving tools in a surgery patient or, for example, allowing a suicidal patient to leave a hospital alone within a matter of hours after he was brought to the hospital after expressing a desire to commit suicide. *See Squeo v. Norwalk Hosp. Ass'n*, 316 Conn. 558, 562, 113 A.3d 932, 936 (2015).

Moreover, the "gross negligence" test requires the absence of "even slight or scant care or slight diligence." *Riccio*, 341 Conn. at 784. Dr. Rizvi and the other Defendants indisputably exercised care far in excess of that standard by, among other things, examining Ms. Mills (despite the suspicion that she had COVID-19), and ordering tests.

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[34] This case presents irrefutable evidence of that fact because Ms. Mills, who had more medical knowledge than the average lay person as a result of her work in an emergency room, did not believe she was having a heart attack even when Dr. Adams thought that might be the case. (RA86 ("She is . . . resistant to my concerns that she may be having an MI." (*i.e.*, a myocardial infarction (a heart attack)).)

The Defendants also exercised care far in excess of that standard and demonstrated significant care for Ms. Mills and other patients and diligence by attempting to determine whether Ms. Mills really needed further treatment or whether she had COVID-19 in order to protect Ms. Mills, staff, and thus other patients, from exposure to COVID-19.

At best for Plaintiff, Plaintiff contends that four separate doctors all committed an error, which does not constitute "gross negligence" as a matter of law (and is something that Defendants obviously vehemently dispute). There is no "gross negligence" here.

I. Plaintiff's Argument That The Trial Court Could Not Decide Immunity Is Meritless

As Plaintiff concedes, our Courts may decide motions to dismiss based on "the complaint supplemented by undisputed facts in the record." *Conboy v. State*, 292 Conn. 642, 651, 974 A.2d 669, 676 (2009).

In such a situation, "if the complaint [is] supplemented by *undisputed facts* established by affidavits submitted in support of the motion to dismiss [and] other types of evidence[,] the trial court, in determining the jurisdictional issue, may consider these supplementary undisputed facts and need not conclusively presume the validity of the allegations of the complaint." *Id.* at 651–52 (citations and internal quotation marks omitted). "Rather, those allegations are tempered by the light shed on them by the supplementary undisputed facts." *Id.* at 652 (internal quotation marks omitted). "If affidavits and/or other evidence submitted in support of a defendant's motion to dismiss conclusively establish that jurisdiction is lacking, and the plaintiff fails to undermine this conclusion with counteraffidavits or other evidence, the trial court may dismiss the action without further proceedings." *Id.* (citations omitted).

In this case, Plaintiff's Complaint ignored the many ways COVID-19 affected Ms. Mills' treatment. (*See* CA9–33; Pl. Br. 9

(admitting as much).) The Defendants submitted extensive evidence—including numerous affidavits and Ms. Mills' medical records—establishing that COVID-19 directly and materially impacted Ms. Mills' treatment from the outset, that doctors' decisions were driven in substantial part by their well-founded belief that Ms. Mills may have had COVID-19, and that Defendants were providing "health care services in support of the State's COVID-19 response" (including, as noted above, with respect to Ms. Mills directly). (*See, e.g.*, RA63.)

Plaintiff did not proffer any counteraffidavits or any other evidence to dispute those facts. She cited Ms. Mills' medical records, which supported the Defendants' Motions to Dismiss by noting many of the ways in which COVID-19 affected Ms. Mills' treatment. She also attached an affidavit from her expert that, rather than disputing any of the facts listed above, contained a single reference to COVID-19 asserting that doctors were still expected to send patients they diagnosed as having a STEMI to the Cath Lab right away during the pandemic. (*See* PA73.) In other words, Plaintiff did not dispute the facts relevant to immunity, which concerned whether doctors were providing "health care services in support of the State's COVID-19 response" and/or whether and how COVID-19 affected Ms. Mills' treatment, including the fact that COVID-19 directly and materially affected Ms. Mills' diagnosis.

At best for Plaintiff, Plaintiff's evidence showed that in a different case with different facts, where doctors had determined that Ms. Mills was having a heart attack, they should have sent her to the Cath Lab right away. But that did not change anything related to the Defendants' Motion to Dismiss, which correctly pointed out that Defendants had immunity regardless of whether they were "wrong."

The Trial Court therefore correctly granted the Defendants' Motions under *Conboy*: Plaintiff failed to present evidence rebutting the facts relevant to immunity, which rendered those facts undisputed.

Plaintiff's argument to the contrary focuses on her allegation that the Defendants "misdiagnosed" Ms. Mills. Even if that were true, however, that does not change the facts relevant to immunity. As previously discussed, immunity turns on whether doctors were providing "health care services in support of the State's COVID-19 response" and/or whether and how COVID-19 affected Ms. Mills' treatment. It does not, and cannot turn on whether doctors were actually correct because any such immunity would be useless.

Plaintiff's argument seeks to deprive the Defendants of their immunity from suit by asserting that facts irrelevant to immunity were somehow relevant to that issue. This Court should not be fooled.

5. CONCLUSION

This is a simple case. A doctor believed based on well-informed bases that a patient may have had COVID-19. In order to slow the spread of the pandemic, and consistent with hospital COVID-19 policies, he therefore pulled the patient aside to determine whether the patient actually needed treatment that would expose others to COVID-19 if she had it or whether the patient's treatment could be deferred. Plaintiff argues that the determination the doctor and other doctors reached was wrong, but that does not change the fact that the determination was made as part of efforts to slow the spread of the pandemic and was materially affected by the pandemic. This is a clear cut case where Governor Lamont intended immunity to apply. It is also a clear cut case for immunity under the PREP Act given the fact that Plaintiff's claims are inextricably intertwined with a doctor's belief that Plaintiff more likely had COVID-19 than a heart attack (the alleged "misdiagnosis") and therefore needed a COVID-19 test.

This Court should affirm the Trial Court's judgment in favor of Defendants Drs. Rizvi, Ferraro-Borgida, and Duncan and, for the reasons set forth in Hartford Healthcare's and Dr. Farrell's briefs in their appeals, reverse the order of the Trial Court insofar as it denied Hartford Healthcare's and Dr. Farrell's Motions to Dismiss in part.

Respectfully submitted,
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CERTIFICATION OF SERVICE AND COMPLIANCE

The undersigned attorney hereby certifies, pursuant to Connecticut Rule of Appellate Procedure § 67-2A, that on January 23, 2023:

(1) the electronically submitted brief and appendix has been delivered electronically to the last known e-mail address of each counsel of record for whom an e-mail address has been provided;

(2) the brief and appendix being filed with the appellate clerk are true copies of the brief and appendix that were submitted electronically;

(3) the electronically submitted brief and appendix and the filed paper brief and appendix have been redacted or do not contain any names or other personal identifying information that is prohibited from disclosure by rule, statute, court order or case law;

(4) the brief contains 11,935 words; and

(5) the brief complies with all provisions of this rule; no deviations were requested.

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CERTIFICATION OF MAILING

The undersigned attorney hereby certifies, pursuant to Connecticut Rule of Appellate Procedure § 67-2, that on January 23, 2023, a copy of the brief and appendix has been sent via electronic mail and U.S. Mail First Class to each counsel of record, *pro se* party, and the Trial Judge who rendered a decision that is the subject matter of the appeal, as follows:

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Filed Under the Electronic Briefing Rules

SUPREME COURT

OF THE

STATE OF CONNECTICUT

S.C. 20765

KRISTIN MILLS, ADMINISTRATOR (ESTATE OF CHERYL MILLS)
Plaintiff-Appellee

v.

HARTFORD HEALTHCARE CORPORATION, ET AL.
Defendants-Appellants

Appendix of the Defendants-Appellants
Asad Rizvi, M.D. and Hartford Healthcare Corporation

For the Defendants-Appellants
Asad Rizvi, M.D. and Hartford Healthcare Corporation

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To be argued by: Brendan N. Gooley

Filed: January 23, 2023

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STATE OF CONNECTICUT

BY HIS EXCELLENCY

NED LAMONT

EXECUTIVE ORDER NO. 7U

PROTECTION OF PUBLIC HEALTH AND SAFETY DURING COVID-19 PANDEMIC AND RESPONSE – PROTECTIONS FROM CIVIL LIABILITY FOR HEALTHCARE PROVIDERS AND BILLING PROTECTIONS FOR PATIENTS

WHEREAS, on March 10, 2020, I issued a declaration of public health and civil preparedness emergencies, proclaiming a state of emergency throughout the State of Connecticut as a result of the coronavirus disease 2019 (COVID-19) outbreak in the United States and confirmed spread in Connecticut; and

WHEREAS, pursuant to such declaration, I have issued twenty-one (21) executive orders to suspend or modify statutes and to take other actions necessary to protect public health and safety and to mitigate the effects of the COVID-19 pandemic; and

WHEREAS, COVID-19 is a respiratory disease that spreads easily from person to person and may result in serious illness or death; and

WHEREAS, the World Health Organization has declared the COVID-19 outbreak a pandemic; and

WHEREAS, the risk of severe illness and death from COVID-19 appears to be higher for individuals who are 60 years of age or older and for those who have chronic health conditions; and

WHEREAS, to reduce the spread of COVID-19, the United States Centers for Disease Control and Prevention and the Connecticut Department of Public Health recommend implementation of community mitigation strategies to increase containment of the virus and to slow transmission of the virus, including cancellation of gatherings of ten people or more and social distancing in smaller gatherings; and

WHEREAS, Section 38a-477aa of the Connecticut General Statutes addresses health care provider reimbursements for emergency services and surprise bills; and

WHEREAS, Sections 19a-508c(l) of the Connecticut General Statutes addresses hospital reimbursements for facility fees; and

WHEREAS, Section 19a-673 of the Connecticut General Statutes addresses maximum hospital charge amounts for uninsured patients; and

WHEREAS, in order to respond adequately to the public health emergency posed by the COVID-19 pandemic, it has been necessary to supplement Connecticut's health care workforce and the capacity of health care facilities to deliver life-saving care by requesting the assistances of health care professionals who have not previously maintained liability coverage; facilitating the deployment of volunteer and out-of-state healthcare professionals; and calling upon healthcare professionals to perform acts that they would not perform in the ordinary course of business; and

WHEREAS, in order to encourage maximum participation in efforts to expeditiously expand Connecticut's health care workforce and facilities capacity, there exists a compelling state interest in affording such professionals and facilities protection against liability for good faith actions taken in the course of their significant efforts to assist in the state's response to the current public health and civil preparedness emergency; and

WHEREAS, no Connecticut resident should have to choose between health and their financial security; and

WHEREAS, health insurance carriers anticipate future health expenditures in their plan design, including premium and cost-sharing allocations, but the current public health emergency will result in significant unexpected health care costs to consumers and health carriers; and

WHEREAS, it is in the public interest to mitigate the adverse impact on consumers' financial security that may result from treatment for COVID-19, as well as to limit the likely premium increases facing consumers in 2021 as a result of the COVID-19 response;

NOW, THEREFORE, I, NED LAMONT, Governor of the State of Connecticut, by virtue of the authority vested in me by the Constitution and the laws of the State of Connecticut, do hereby **ORDER AND DIRECT:**

1. **Protection from Civil Liability for Actions or Omissions in Support of the State's COVID-19 Response.** Notwithstanding any provision of the Connecticut General Statutes, or any associated regulations, rules, policies, or procedures, any health care professional or health care facility shall be immune from suit for civil liability for any injury or death alleged to have been sustained because of the individual's or health care facility's acts or omissions undertaken in good faith while providing health care services in support of the State's COVID-19 response, including but not limited to acts or omissions undertaken because of a lack of resources, attributable to the COVID-19 pandemic, that renders the health care professional or health care facility unable to provide the level or manner of care that otherwise would have been required in the absence of the COVID-19 pandemic and which resulted in the damages at issue, provided that nothing in this order shall remove or limit any immunity conferred by any provision of the Connecticut General Statutes or other law. Such immunity shall not extend to acts or omissions that constitute a crime, fraud, malice, gross negligence, willful misconduct, or would otherwise constitute a false claim or prohibited act pursuant to Section 4-275 et seq.

of the Connecticut General Statutes or 31 U.S.C. §§3729 et seq. The term "health care professional" means an individual who is licensed, registered, permitted, or certified in any state in the United States to provide health care services and any retired professional, professional with an inactive license, or volunteer approved by the Commissioner of the Department of Public Health or her designee. The term "health care facility" means a licensed or state approved hospital, clinic, nursing home, field hospital or other facility designated by the Commissioner of the Department of Public Health for temporary use for the purposes of providing essential services in support of the State's COVID-19 response. The immunity conferred by this order applies to acts or omissions subject to this order occurring at any time during the public health and civil preparedness emergency declared on March 10, 2020, including any period of extension or renewal, including acts or omissions occurring prior to the issuance of this order attributable to the COVID-19 response effort.

2. **Financial Protections for the Uninsured and People Covered by Insurance Who Receive Out-of-Network Health Care Services During the Public Health Emergency.** Effective immediately and for the duration of the public health and civil preparedness emergency declared on March 10, 2020, including any period of extension or renewal:

    a. Section 38a-477aa(b)(3)(A) of the Connecticut General Statutes is modified to provide: "If emergency services were rendered to an insured by an out-of-network health care provider, such health care provider may bill the health carrier directly and the health carrier shall reimburse such health care provider the amount the insured's health care plan would pay for such services if rendered by an in-network health care provider as payment in full."

    b. Section 38a-477aa(b)(3)(B) of the Connecticut General Statutes is suspended.

    c. Section 19a-673(b) of the Connecticut General Statutes is modified to provide: "No hospital that has provided health care services to an uninsured patient may collect from the uninsured patient more than the cost of providing services, except that, for uninsured patients receiving services for the treatment and management of COVID-19, no hospital may collect from the uninsured patient or such patient's estate more than the Medicare rate for said services as payment in full."

    d. Section 19a-508c(l) of the Connecticut General Statutes is modified to additionally provide: "Notwithstanding the provisions of this section, no hospital, health system or hospital-based facility shall collect a facility fee

for services received by a patient for the treatment and management of COVID-19 who is uninsured of more than the Medicare rate."

e. No hospital shall bill any individual not otherwise covered by any public or private health plan for services received for treatment and management of COVID-19, unless and until clarified by further executive order regarding distribution of any federal funding that may be made available to cover such services.

f. Each hospital, health system or hospital-based facility shall maintain fiscal records to identify services provided to uninsured patients for treatment and management of COVID-19 and make such records available for claiming federal reimbursement, as applicable.

Unless otherwise specified herein, this order shall take effect immediately and shall remain in effect for the duration of the public health and civil preparedness emergency, unless earlier modified or terminated by me.

Dated at Hartford, Connecticut, this 5th day of April, 2020.

Ned Lamont
Governor

By His Excellency's Command

Denise W. Merrill
Secretary of the State

STATE OF CONNECTICUT

BY HIS EXCELLENCY

NED LAMONT

EXECUTIVE ORDER NO. 7V

PROTECTION OF PUBLIC HEALTH AND SAFETY DURING COVID-19 PANDEMIC AND RESPONSE – SAFE WORKPLACES, EMERGENCY EXPANSION OF THE HEALTHCARE WORKFORCE

WHEREAS, on March 10, 2020, I issued a declaration of public health and civil preparedness emergencies, proclaiming a state of emergency throughout the State of Connecticut as a result of the coronavirus disease 2019 (COVID-19) outbreak in the United States and confirmed spread in Connecticut; and

WHEREAS, pursuant to such declaration, I have issued twenty-two (22) executive orders to suspend or modify statutes and to take other actions necessary to protect public health and safety and to mitigate the effects of the COVID-19 pandemic; and

WHEREAS, COVID-19 is a respiratory disease that spreads easily from person to person and may result in serious illness or death; and

WHEREAS, the World Health Organization has declared the COVID-19 outbreak a pandemic; and

WHEREAS, the risk of severe illness and death from COVID-19 appears to be higher for individuals who are 60 years of age or older and for those who have chronic health conditions; and

WHEREAS, to reduce the spread of COVID-19, the United States Centers for Disease Control and Prevention and the Connecticut Department of Public Health recommend implementation of community mitigation strategies to increase containment of the virus and to slow transmission of the virus, including cancellation of gatherings of ten people or more and social distancing in smaller gatherings; and

WHEREAS, the critical need to limit the spread of COVID-19 requires the enforcement of distancing and other protective measures in all workplaces; and

WHEREAS, numerous medical professionals, after having completed the educational requirements for their profession, are permitted to temporarily practice their profession under the supervision of a licensed practitioner prior to being licensed; and

WHEREAS, such professionals' ability to temporarily practice their profession may expire prior to the end of the public health and civil preparedness emergency; and

WHEREAS, necessary public health protective measures enacted in response to the COVID-19 pandemic may prevent such professionals from completing their licensing requirements during the public health and civil preparedness emergency; and

WHEREAS, to maintain and expand the healthcare workforce capacity for COVID-19 response and mitigation efforts, it is necessary to allow such professionals to continue to work in such temporary, supervised status for the duration of the declared civil preparedness and public health emergency; and

WHEREAS, as a result of the dire economic effects of the necessary public health protective measures enacted in response to the COVID-19 pandemic, an unprecedented number of Connecticut residents have filed for unemployment benefits; and

WHEREAS, to reduce burdens on contributing employers whose employees have had to file unemployment claims as a result of COVID-19, it is necessary to relieve those employers of the amount of benefit payments charged to an employer's experience account; and

WHEREAS, there exists a compelling state interest in rapidly expanding the capacity of health care professionals and facilities to provide care during the COVID-19 pandemic; and

WHEREAS, providing relief from liability for such health care professionals for good faith efforts to provide care during the COVID-19 pandemic will greatly increase the state's ability to achieve such an expansion;

NOW, THEREFORE, I, NED LAMONT, Governor of the State of Connecticut, by virtue of the authority vested in me by the Constitution and the laws of the State of Connecticut, do hereby **ORDER AND DIRECT:**

1. **Safe Workplaces in Essential Businesses.** Every workplace in the State of Connecticut shall take additional protective measures to reduce the risk of transmission of COVID-19 between and among employees, customers, and other persons such as delivery drivers, maintenance people or others who may enter the workplace. The Commissioner of Economic and Community Development, in consultation with the Commissioner of Public Health, shall issue legally binding statewide rules prescribing such additional protective measures no later than 5:00 p.m. on April 7, 2020. Such rules shall be mandatory throughout the state, for essential businesses and nonprofits and any other business or nonprofit permitted to operate, and shall supersede and preempt any current or future municipal order. Nothing in such rules or this order shall supersede Executive Order No. 7S, Section 1, or the "Safe Stores" rules promulgated thereunder.

2. **Temporary Permits for Certain Health Care Providers Extended and Fees Waived.** Sections 20-65k, 20-12b(b), 20-74d, 20-162o(c) and 20-195t of the Connecticut General Statutes are modified to waive any application fees for temporary permits and to extend the duration of the temporary permits for the health care professions governed thereunder (Athletic Trainer, Respiratory Care Practitioner, Physician Assistant, Occupational, Therapist/Assistants, Master Social Worker), for

the duration of the public health and civil preparedness emergency, unless earlier modified or terminated. The Commissioner may issue any implementing order she deems necessary to effectuate this order.

3. **Practice Before Licensure for Certain Health Care Profession Applicants and Graduates.** The provisions in Sections 20-70(b)(1), 20-70(b)(2), 20-74bb(f), and 20-101 of the Connecticut General Statutes that permit practice prior to licensure by applicants and graduates for the health care professions governed thereunder (Physical Therapist, Physical Therapy Assistant, Radiographer, Registered Nurse, Nurse Practitioner, Clinical Nurse Specialist, Nurse Anesthetist), are modified to permit such practice for the duration of the public health and civil preparedness emergency, unless earlier modified or terminated. The Commissioner of Public Health may issue any implementing orders she deems necessary to effectuate this order.

4. **Practice Before Licensure for Marital and Family Therapy Associates.** Section 20-195f of the Connecticut General Statutes is modified to provide that, for the duration of the public health and civil preparedness emergency, unless earlier modified or terminated, no license shall be required to practice as a marital and family therapy associate, as defined in Section 20-195a(4), for a person who has completed a graduate degree program specializing in marital and family therapy offered by a regionally accredited institution of higher education or a postgraduate clinical training program accredited by the Commission on Accreditation for Marriage and Family Therapy Education and offered by a regionally accredited institution of higher education. The Commissioner may issue any implementing orders she deems necessary to effectuate this order.

5. **Practice Before Licensure for Professional Counselor Associates.** Section 20-195bb(c) of the Connecticut General Statutes is modified to permit a person who has completed the requirements in Section 20-195dd(b) to practice as a professional counselor associate without obtaining a license for the duration of the public health and civil preparedness emergency, unless earlier modified or terminated. The Commissioner may issue any implementing orders she deems necessary to effectuate this order.

6. **Executive Order No. 7U, Section 1, Superseded - Protection from Civil Liability for Actions or Omissions in Support of the State's COVID-19 Response.** Section 1 of my prior Executive Order No. 7U concerning protection from civil liability for actions or omissions in support of the State's COVID-19 response is hereby superseded and replaced in its entirety by the following:

   Notwithstanding any provision of the Connecticut General Statutes or any other state law, including the common law, or any associated regulations, rules, policies, or procedures, any health care professional or health care facility shall be immune from suit for civil liability for any injury or death alleged to have been sustained because of the individual's or health care facility's acts or omissions undertaken in good faith while providing health care services in support of the State's COVID-19 response, including

but not limited to acts or omissions undertaken because of a lack of resources, attributable to the COVID-19 pandemic, that renders the health care professional or health care facility unable to provide the level or manner of care that otherwise would have been required in the absence of the COVID-19 pandemic and which resulted in the damages at issue, provided that nothing in this order shall remove or limit any immunity conferred by any provision of the Connecticut General Statutes or other law. Such immunity shall not extend to acts or omissions that constitute a crime, fraud, malice, gross negligence, willful misconduct, or would otherwise constitute a false claim or prohibited act pursuant to Section 4-275 et seq. of the Connecticut General Statutes or 31 U.S.C. §§3729 et seq. The term "health care professional" means an individual who is licensed, registered, permitted, or certified in any state in the United States to provide health care services and any retired professional, professional with an inactive license, or volunteer approved by the Commissioner of the Department of Public Health or her designee. The term "health care facility" means a licensed or state approved hospital, clinic, nursing home, field hospital or other facility designated by the Commissioner of the Department of Public Health for temporary use for the purposes of providing essential services in support of the State's COVID-19 response. The immunity conferred by this order applies to acts or omissions subject to this order occurring at any time during the public health and civil preparedness emergency declared on March 10, 2020, including any period of extension or renewal, including acts or omissions occurring prior to the issuance of this order attributable to the COVID-19 response effort.

Unless otherwise specified herein, this order shall take effect immediately and shall remain in effect for the duration of the public health and civil preparedness emergency, unless earlier modified or terminated by me.

Dated at Hartford, Connecticut, this 7th day of April, 2020.

Ned Lamont
Governor

By His Excellency's Command

Denise W. Merrill
Secretary of the State

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of "Covered Countermeasures" and "qualified pandemic and epidemic products" in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html*, accessed 27Feb2020,

(Recommended Activities). In Section III of the Declaration, the Secretary sets out the activities for which the immunity is in effect.

Section IV. Limited Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, "[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure." In Section IV of the Declaration, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including Qualified Persons. The PREP Act defines Covered Persons to include, among others, the United States, and those that manufacturer, distribute, administer, prescribe or use Covered Countermeasures. This Declaration includes all persons and entities defined as Covered Persons under the PREP Act (PHS Act 317F–3(i)(2)) as well as others set out in paragraphs (3), (4), (6), (8)(A) and (8)(B).

The PREP Act's liability immunity applies to "Covered Persons" with respect to administration or use of a Covered Countermeasure. The term "Covered Persons" has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms "manufacturer," "distributor," "program planner," and "qualified person" as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: Manufacturers; re-packers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other "person" can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word "person" as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.

Section VI. Covered Countermeasures

As noted above, Section III of the Declaration describes the activities (referred to as "Recommended Activities") for which liability immunity is in effect. Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended such activities. The PREP Act states that a "Covered Countermeasure" must be a "qualified pandemic or epidemic product," or a "security countermeasure," as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device.

A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists medical countermeasures against COVID–19 that

are Covered Countermeasures under this declaration.

Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII. Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency.

Section VII defines the terms "Authority Having Jurisdiction" and "Declaration of an emergency." We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII. Category of Disease, Health Condition, or Threat

The Secretary must identify in the Declaration, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII of the Declaration, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV-2 or a virus mutating therefrom.

Section IX. Administration of Covered Countermeasures

The PREP Act does not explicitly define the term "administration" but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX of the Declaration, the Secretary defines "Administration of a Covered Countermeasure," as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of "administration" extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X. Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. Section X of the Declaration identifies which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes "any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration."

It should be noted that under the PREP Act, liability protection extends beyond the Population specified in the Declaration. Specifically, liability immunity is afforded (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population, and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XI. Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect, including, as appropriate, whether the Declaration applies only to

individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI of the Declaration provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in countries outside the U.S. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded (1) to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas, and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XII. Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII of the Declaration extends the effective period for different means of distribution of Covered Countermeasures through October 1, 2024.

Section XIII. Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including accepting returns of Covered Countermeasures, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that, for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d-6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continue during these additional time periods. Thus, liability immunity is afforded during the "Effective Time Period," described under Section XII of the Declaration, plus the "Additional Time Period" described under Section XIII of the Declaration.

Section XIII of the Declaration provides for 12 months as the Additional Time Period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any product obtained for the SNS during the effective period of the Declaration.

Section XIV. Countermeasures Injury Compensation Program

Section 319F–4 of the PHS Act, 42 U.S.C. 247d-6e, authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires "compelling, reliable, valid, medical and scientific evidence." The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV of the Declaration, "Countermeasures Injury Compensation Program," explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify that if countermeasures are administered or used outside the United States, only otherwise eligible individuals at United States embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV. Amendments

Section XV of the Declaration confirms that the Secretary may amend any portion of this Declaration through publication in the **Federal Register**.

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS-CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and

volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

As used in this Declaration, the terms Authority Having Jurisdiction and Declaration of Emergency have the following meanings:

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.

ii. A Declaration of Emergency means any Declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal Declaration in support of an Emergency Use Authorization under Section 564 of the FD&C Act unless such Declaration specifies otherwise;

I have also determined that, for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV–2 or a virus mutating therefrom.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through October 1, 2024.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: March 10, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–05484 Filed 3–12–20; 4:15 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–18–423: NIDDK Multi-Center Clinical Study Implementation Planning Cooperative Agreements (U34) in Digestive Diseases.

Date: May 22, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–7682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 10, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05361 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Small Business: Cardiovascular Sciences, March 19, 2020 08:00 a.m. to March 20, 2020, 01:00 p.m., Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314 which was published in the **Federal Register** on February 20, 2020, 85 FR 9791.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, at 09:00 a.m. The meeting date remains the same. The meeting is closed to the public.

Dated: March 11, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05417 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, PAR 19–059: Global Noncommunicable Diseases and Injury Across the Lifespan (R21), March 23, 2020, 8:00 a.m. to 5:00 p.m., at the Hotel Palomar, 2121 P Street NW, Washington, DC 20037, which was published in the **Federal Register** on February 25, 2020, 85 FR 10708.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The format of the meeting has been changed to a Video Assisted Meeting. The meeting date and time remain the same. The meeting is closed to the public.

Dated: March 11, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05419 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer Clinical Centers Special Emphasis Panel.

Date: April 2, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

DOCKET # HHD-CV20-6134761-S	:	SUPERIOR COURT
	:	
KRISTIN MILLS, ADMINISTRATOR OF THE ESTATE OF CHERYL MILLS,	:	J.D. OF HARTFORD
Plaintiff,	:	
	:	
v.	:	AT HARTFORD
	:	
HARTFORD HEALTHCARE CORPORATION, d/b/a HARTFORD HOSPITAL; ASAD RIZVI, M.D.; MELISSA FERRARO-BORGIDA, M.D.; BRETT H. DUNCAN, M.D.; and WILLIAM FARRELL, M.D.,	:	
Defendants.	:	JANUARY 12, 2021

AFFIDAVIT OF DR. ADAM STEINBERG

I, Adam Steinberg, D.O., being duly sworn, depose and state:

1. I am over the age of eighteen (18) and understand the obligations of an oath.

2. I am a physician licensed to provide health care services in the State of Connecticut. I am currently Vice President for Medical Affairs, Hartford Region at Hartford HealthCare Corporation.

3. I make this affidavit in support of Hartford HealthCare Corporation d/b/a Hartford's Hospital's and Dr. Asad Rizvi's motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.

4. I am familiar with the treatment of Cheryl Mills ("Ms. Mills") from March 21, 2020 through March 25, 2020 (the "Treatment Period") and have reviewed Ms. Mills's medical records that were produced during the Treatment Period.

5. At all times relevant to this action, including the Treatment Period, Hartford

HealthCare Corporation, including all of its affiliated hospitals and its agents and employees, was providing health care services in support of the State of Connecticut's response to the ongoing global pandemic caused by the SARS-CoV-2 virus and the associated respiratory illness known as COVID-19. Such response included treating patients infected with or suspected of being infected with COVID-19, as well as taking steps to prevent or limit the spread of COVID-19 to patients receiving treatment for other conditions.

6. During the Treatment Period, the northeastern United States, including Connecticut, was confronted with rapidly-increasing numbers of individuals infected with COVID-19.

7. During the Treatment Period, HHC was engaged in various steps to conserve personal protective equipment ("PPE"), including, but not limited to, minimizing in-person contact between patients and hospital personnel and limiting the number of hospital personnel in contact with patients suspected of having COVID-19.

8. As a result of COVID-19 concerns generally as well as PPE-related concerns specifically, HHC modified its protocols to, among other things, 1) avoid administration of echocardiograms to patients who did not demonstrate an absolute clinical need and 2) avoid admitting patients who were suspected of having COVID-19 to Hartford Hospital's Cardiac Catheterization lab (the "Cath Lab") until they had tested negative, unless their physical symptoms dictated the need for emergency catheterization.

9. Ms. Mills's medical records indicate that she presented to the Backus Hospital Emergency Department (the "Backus ED") on March 21, 2020, complaining of a sore throat and a headache, both of which had lasted approximately three days, and stating that her granddaughter was recently ill with strep throat. A true and accurate copy of this record is

attached hereto as Exhibit A.

10. Ms. Mills's medical records further indicate that, at the time she presented to the Backus ED at the outset of the Treatment Period, she was an employee of the Backus ED. A true and accurate copy of one such record is attached hereto as Exhibit B.

11. Ms. Mills's medical records indicate that Ms. Mills's treating physician in the Backus ED contacted Dr. Asad Rizvi, who was at that time the on-call attending physician in the Cath Lab, due to concerns relating to Ms. Mills's electrocardiogram (EKG) results and to coordinate possible transfer to Hartford Hospital. *See* Exhibit A.

12. Ms. Mills's medical records indicate, among other things, that Dr. Rizvi was concerned that Ms. Mills may have been infected with COVID-19. *See* Exhibits A, B.

13. Ms. Mills's medical records indicate that for multiple reasons, including but not limited to suspicion that she was experiencing a viral syndrome, Dr. Rizvi recommended that Ms. Mills be transferred from the Backus ED to the Hartford Hospital Emergency Department, rather than sent directly to the Cath Lab. *See* Exhibits A, B.

14. Ms. Mills's medical records further indicate that, given her clinical presentation, it was recommended that she be placed in isolation upon her arrival to Hartford Hospital and that any possible COVID-19 infection be ruled out. *See* Exhibit B.

15. Ms. Mills's medical records indicate that, following her arrival to Hartford Hospital, she was given a clinical test for COVID-19 at approximately 5:18 P.M. on March 21, 2020. This test was sent for analysis to the Connecticut State Public Health Laboratory, pursuant to testing protocols then in place. A true and accurate copy of this record is attached hereto as Exhibit C.

16. Ms. Mills's medical records indicate that her COVID-19 test results did not come

back until March 24, 2020 at approximately 7:40 P.M, at which time the test indicated a negative result for COVID-19. A true and accurate copy of this record is attached as Exhibit D.

Adam Steinberg, D.O.
Vice President for Medical Affairs, Hartford Region
at Hartford HealthCare Corp.

STATE OF CONNECTICUT:

:

COUNTY OF HARTFORD :

Subscribed and sworn to before me
this 12th day of January, 2021.

Commissioner of the Superior Court
Notary Public
My Commission Expires:

ANNA JARNUTOWSKI
NOTARY PUBLIC - CT 178195
MY COMMISSION EXPIRES JANUARY 31, 2024

DOCKET # HHD-CV20-6134761-S	:	SUPERIOR COURT
	:	
KRISTIN MILLS, ADMINISTRATOR OF THE ESTATE OF CHERYL MILLS,	:	J.D. OF HARTFORD
Plaintiff,	:	
	:	
v.	:	AT HARTFORD
	:	
HARTFORD HEALTHCARE CORPORATION, d/b/a HARTFORD HOSPITAL; ASAD RIZVI, M.D.; MELISSA FERRARO-BORGIDA, M.D.; BRETT H. DUNCAN, M.D.; and WILLIAM FARRELL, M.D.,	:	
Defendants.	:	JANUARY 13, 2021

AFFIDAVIT OF ASAD RIZVI, M.D.

I, Asad Rizvi, M.D., being duly sworn, depose and state:

1. I am over the age of eighteen (18) and understand the obligations of an oath.

2. I am a physician licensed to provide health care services in the State of Connecticut. I am currently employed as an interventional cardiologist at Hartford Hospital in Hartford, Connecticut, and in that position work within Hartford Hospital's cardiac catheterization laboratory (the "Cath Lab").

3. I make this affidavit in support of Hartford HealthCare Corporation d/b/a Hartford's Hospital's and my motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.

4. I provided medical treatment to Plaintiff's Decedent, Cheryl Mills ("Ms. Mills") on March 21, 2020. Specifically, my treatment involved corresponding with Ms. Mills's treating physician in the Backus Hospital Emergency Department (the "Backus ED") regarding Ms.

Mills's clinical presentation; reviewing the results of Ms. Mills's clinical tests, including electrocardiogram (EKG) results and echocardiogram results; personally examining Ms. Mills upon her arrival to Hartford Hospital; and recommending a COVID-19 test for Ms. Mills based upon her presentation.

5. Based on my medical training and experience, I know that certain viral infections can cause myocarditis and myopericarditis and in turn cause patients' EKG results to demonstrate ST elevation.

6. At the time I provided medical treatment to Ms. Mills, I was aware that certain patients afflicted with COVID-19 could present with ST elevation and abnormal troponin levels secondary to COVID-induced myocarditis or myopericarditis.

7. At the time I provided medical treatment to Ms. Mills, the Cath Lab, along with Hartford Hospital generally, had implemented certain protocols and procedures intended to minimize staff exposure to patients possibly infected with COVID-19 and preserve personal protective equipment ("PPE"), as well as to avoid cross-infecting patients who were not infected with COVID-19.

8. Based on the entirety of Ms. Mills's clinical presentation while I was treating her, including, but not limited to, her high risk for exposure to COVID-19 based on her employment as a registrar in the Backus ED, the nature and duration of symptoms upon presentation which were consistent with a viral infection, and the notable absence of cardiac symptoms upon presentation, I believed, based on my medical training and expertise, that Ms. Mills could be experiencing a cardiac inflammatory condition such as myocarditis or myopericarditis secondary to a viral syndrome, and that this viral syndrome was possibly COVID-19.

9. Given my concern that Ms. Mills was infected with COVID-19, combined with

her lack of symptoms of an ST elevation myocardial infarction and the absence of physical examination findings suggestive of an ST elevation myocardial infarction, I determined, based on my medical training and expertise, that the most prudent course of action in light of the infectious disease protocols at that time given the COVID-19 treatment environment was to delay Ms. Mills's admission to the Cath Lab pending receipt of the results of a COVID-19 test that was administered to her shortly after her arrival to Hartford Hospital.

Asad Rizvi, M.D.

STATE OF CONNECTICUT:
:
COUNTY OF HARTFORD :

Subscribed and sworn to before me
this 13th day of January, 2021.

Darlene L Rolmer

~~Commissioner of the Superior Court~~
Notary Public
My Commission Expires: 9/30/2025

DOCKET NO: HHD-CV-20-6134761-S	: SUPERIOR COURT
KRISTIN MILLS, ADMINISTRATOR OF THE ESTATE OF CHERYL MILLS	: J.D. OF HARTFORD
VS.	: AT HARTFORD
HARTFORD HEALTHCARE CORPORATION D/B/A HARTFORD HOSPITAL, ET AL	: JANUARY 11, 2021

AFFIDAVIT

I, William Farrell, MD, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.

2. I am a board-certified in cardiovascular medicine and interventional cardiology and a licensed physician in the State of Connecticut, and had privileges to provide care and treatment to patients at Hartford Hospital during the timeframe at issue in this lawsuit.

3. I make this affidavit in support of the motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records relating to the treatment period at issue in this lawsuit.

4. I was involved in the care and treatment of plaintiff's decedent on March 23 – March 25, 2020. At the time of my care and treatment the COVID-19 pandemic was affecting the diagnosis and management of cardiovascular disease patients. My assessment, differential diagnosis, and care and treatment of plaintiff's decedent was significantly influenced and dictated by the COVID-19 pandemic.

5. COVID-19 was a primary factor in my diagnostic assessment of COVID-19 caused myocarditis versus acute coronary syndrome. At the time of the treatment of plaintiff's decedent

COVID-19 patients were presenting with myocarditis simulating a STEMI presentation thus creating a novel diagnostic assessment. This was particularly true in patients like plaintiff's decedent presenting with sore throat and headache and not chest pain and shortness of breath.

6. As a result of presenting history and clinical presentation, plaintiff's decedent was suspected COVID-19 and therefore the plan already in place was to defer cardiac catherization until receipt of the pending COVID-19 test results. As of the time of my involvement in the care and treatment of plaintiff's decedent the timing of the cardiac catheterization was dictated and determined by the need to rule out COVID-19.

7. Attached hereto are true copies of my contemporaneous treatment notes and discharge summary clearly delineating that my assessment of differential diagnosis and the timing of cardiac catheterization was significantly dictated by the COVID-19 pandemic.

William Farrell, MD

STATE OF CONNECTICUT)
) ss. New Haven
COUNTY OF)

Subscribed and sworn to before me, this 11th day of January, 2021.

Notary Public
My Commission Expires:
Commissioner of the Superior Court

Lorraine Molinari
NOTARY PUBLIC
State of Connecticut
My Commission Expires 8/31/2024

DOCKET NO: HHD-CV-20-6134761-S	: SUPERIOR COURT
KRISTIN MILLS, ADMINISTRATOR OF THE ESTATE OF CHERYL MILLS	: J.D. OF HARTFORD
VS.	: AT HARTFORD
HARTFORD HEALTHCARE CORPORATION D/B/A HARTFORD HOSPITAL, ET AL	: MAY 5, 2021

AFFIDAVIT

I, William Farrell, MD, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.

2. I am a board-certified in cardiovascular medicine and interventional cardiology and a licensed physician in the State of Connecticut, and had privileges to provide care and treatment to patients at Hartford Hospital during the timeframe at issue in this lawsuit.

3. I make this affidavit in support of the motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records relating to the treatment period at issue in this lawsuit.

4. On March 25, 2020 at 6:06 am, in response to the resulting, after hours, on March 24, 2020 at 7:40 pm of negative COVID-19 results, I issued orders to schedule plaintiff's decedent for coronary angiogram on that day. Attached hereto is a true copy of such order.

5. The issuance of this order was not a new treatment decision and plan, but rather was completion of the treatment plan established on March 21, 2020, dictated as a result of COVID-19 concerns of myocarditis simulating a STEMI presentation and concerns of COVID-19 exposure and spread risk.

6. As dictated by the original plan premised upon COVID-19 concerns, the coronary angiogram was scheduled immediately upon receipt of the negative COVID-19 test so as to evaluate her coronary anatomy based on her risk factors and elevated cardiac enzymes.

7. As dictated by the original COVID-19 based plan, the coronary angiogram was not ordered urgently as a means of PCI (primary percutaneous coronary intervention) for a perceived STEMI patient. This decision was made on March 21, 2020 and the medical records reflect that such decision was significantly impacted by assessment of COVID-19 caused myocarditis versus acute coronary syndrome. As of the time of my care and treatment the initial event, whatever it was, was a completed event.

8. My treatment decisions after receipt of the COVID-19 negative test results were dictated by the plan put in place as a result of COVID-19 concerns and the negative COVID-19 test results did not change the plan put in place.

William Farrell, MD

STATE OF CONNECTICUT)
) ss. Wallingford
COUNTY OF New Haven)

Subscribed and sworn to before me, this 5th day of May, 2021.

Lorraine Molinari
Notary Public
My Commission Expires: 8/31/2024
Commissioner of the Superior Court

DOCKET NO.: HHD CV20 6134761 S	:	SUPERIOR COURT
ESTATE OF CHERYL D. MILLS	:	J.D. OF HARTFORD
V.	:	AT HARTFORD
HARTFORD HEALTHCARE CORP., ET AL.	:	JANUARY 12, 2021

AFFIDAVIT

I, Melissa Ferraro-Borgida, MD, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.
2. I am board-certified in cardiovascular disease and a licensed physician in the State of Connecticut, and had privileges to provide care and treatment to patients at Hartford Hospital during the time frame at issue in this lawsuit.
3. I make this affidavit in support of the defendants' motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.
4. I am familiar with the treatment of Cheryl Mills ("Ms. Mills") from March 21, 2020 through March 25, 2020 (the "Treatment Period") because I was involved in Ms. Mills' care at Hartford Hospital on March 21, 2020 and the early morning hours of March 22, 2020. I have also reviewed Ms. Mills'

medical records that were produced during the Treatment Period.

5. At the time of my care and treatment of Ms. Mills, the COVID-19 pandemic was affecting the diagnosis and management of cardiovascular disease patients. My assessment, differential diagnosis, and care and treatment of Ms. Mills was significantly impacted and directed by the COVID-19 pandemic.

6. During the Treatment Period, patients were presenting with suspected COVID-19 related myocarditis simulating an ST Elevation Myocardial Infarction ("STEMI"), thus creating novel diagnostic and therapeutic challenges for patient assessment (myocarditis is an inflammation of the heart muscle usually caused by a viral infection). This was particularly true in patients like Ms. Mills presenting with sore throat and headache and not chest pain and shortness of breath.

7. Additional concerns had to be factored when making treatment decisions for patients during the Treatment Period, including Ms. Mills, because of the COVID-19 pandemic, such as the conservation of personal protective equipment ("PPE") and preventing the spread of COVID-19 to other patients or to staff, which could have caused a compromise of the health of both patients and staff as well as a workforce shortage.

8. The medical records indicate that Ms. Mills first presented to Backus

Hospital on March 21, 2020 with complaints of a 3-day history of sore throat and headache, and the attending emergency room physician sought to have Ms. Mills transferred to Hartford Hospital due to concerns relating to Ms. Mills' electrocardiogram.

9. The medical records indicate at the time of Ms. Mills' admission to Hartford Hospital on March 21, 2020, she was examined by Dr. Asad Rizvi, who suspected that Ms. Mills may have been infected with COVID-19 and that her presentation was consistent with a COVID-19 induced myocarditis. The plan in place at the time I became involved in Ms. Mills' care was to defer cardiac catheterization until receipt of the pending COVID-19 test results.

10. Based upon multiple factors including but not limited to my assessment of Ms. Mills on March 21 and 22, 2020, the timing of the assessment, and the patient's history, presentation, symptoms, and test results I, in good faith, agreed with the plan to defer cardiac catheterization until a COVID-19 infection was ruled out as is detailed in my contemporaneously created notes of March 21 and 22, 2020 which are attached hereto.

11. COVID-19 was a primary factor in my diagnostic assessment of COVID-19 caused myocarditis versus acute coronary syndrome.

12. The medical records indicate that on March 21, 2020 at approximately 5:18 pm, a polymerase chain reaction ("PCR") COVID-19 test was administered

to Ms. Mills, and the collected specimen was sent to the Connecticut Department of Public Health for testing.

13. The medical records indicate that Ms. Mills' COVID-19 test results were not received until March 24, 2020 at approximately 7:40 P.M, at which time the test indicated a negative result for COVID-19.

Melissa Ferraro-Borgida, MD

STATE OF CONNECTICUT)
) ss. _____
COUNTY OF)

Subscribed and sworn to before me, this 12th day of January, 2021

~~Notary Public~~
~~My Commission Expires:~~
Commissioner of the Superior Court

DOCKET NO.: HHD CV20 6134761 S	:	SUPERIOR COURT
ESTATE OF CHERYL D. MILLS	:	J.D. OF HARTFORD
V.	:	AT HARTFORD
HARTFORD HEALTHCARE CORP., ET AL.	:	MAY 11, 2021

AFFIDAVIT

I, **Melissa Ferraro-Borgida**, MD, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.

2. I am board-certified in cardiovascular disease and a licensed physician in the State of Connecticut, and I had privileges to provide care and treatment to patients at Hartford Hospital during the time frame at issue in this lawsuit.

3. I make this affidavit in support of the defendants' motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.

4. I am familiar with the treatment of Cheryl Mills ("Ms. Mills") from March 21, 2020 through March 25, 2020 (the "Treatment Period") because I

was involved in Ms. Mills' care at Hartford Hospital on March 21, 2020 and the early morning hours of March 22, 2020. I have also reviewed Ms. Mills' medical records that were produced during the Treatment Period.

5. As of the time I became involved in the care and treatment of Ms. Mills, the plan in place was to defer cardiac catheterization until receipt of the pending COVID-19 test results as her presentation was consistent with COVID-19 related myocarditis, and an active COVID-19 infection had to be ruled out.

6. The existing treatment plan in place at the time of my involvement in Ms. Mills' care did not include urgent or emergent transfer to the catheterization lab upon receipt of a negative COVID-19 test.

Melissa Ferraro-Borgida, MD

STATE OF CONNECTICUT)
) ss. _____
COUNTY OF)

Subscribed and sworn to before me, this 11th day of May, 2021.

Notary Public
My Commission Expires:
Commissioner of the Superior Court

DOCKET NO.: HHD CV20 6134761 S	:	SUPERIOR COURT
	:	
ESTATE OF CHERYL D. MILLS	:	J.D. OF HARTFORD
	:	
V.	:	AT HARTFORD
	:	
HARTFORD HEALTHCARE CORP., ET AL.	:	JANUARY 12, 2021

AFFIDAVIT

I, **Brett H. Duncan, MD**, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.
2. I am board-certified in cardiovascular disease and a licensed physician in the State of Connecticut, and had privileges to provide care and treatment to patients at Hartford Hospital during the timeframe at issue in this lawsuit.
3. I make this affidavit in support of the defendants' motion to dismiss the complaint filed by Kristin Mills, Administrator of the Estate of Cheryl Mills, in the above-captioned action. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.
4. I am familiar with the treatment of Cheryl Mills ("Ms. Mills") from

March 21, 2020 through March 22, 2020 because I was involved in Ms. Mills' care at Hartford Hospital on March 22, 2020 (the "Treatment Period").

5. At the time of my care and treatment of Ms. Mills, the COVID-19 pandemic was affecting the diagnosis and management of cardiovascular disease patients. My assessment, differential diagnosis, and care and treatment of Ms. Mills was significantly impacted and directed by the COVID-19 pandemic.

6. During the Treatment Period, patients were presenting with suspected COVID-19 related myocarditis simulating an ST Elevation Myocardial Infarction ("STEMI"), thus creating novel diagnostic and therapeutic challenges for patient assessment (myocarditis is an inflammation of the heart muscle usually caused by a viral infection). This was particularly true in patients like Ms. Mills presenting with sore throat and headache and not chest pain and shortness of breath.

7. On or about March 22, 2020, additional concerns had to be factored when making treatment decisions for patients, including Ms. Mills, because of the COVID-19 pandemic, such as the conservation of personal protective equipment ("PPE") and preventing the spread of COVID-19 to other

patients or to staff, which could have caused a compromise of the health of both patients and staff as well as a workforce shortage.

8. The medical records indicate that Ms. Mills first presented to Backus Hospital on March 21, 2020 with complaints of a 3-day history of sore throat and headache, and the attending emergency room physician sought to have Ms. Mills transferred to Hartford Hospital due to concerns relating to Ms. Mills' electrocardiogram.

9. The medical records indicate at the time of Ms. Mills' admission to Hartford Hospital on March 21, 2020, she was examined by Dr. Asad Rizvi, who suspected that Ms. Mills may have been infected with COVID-19 and that her presentation was consistent with a COVID-19 induced myocarditis. The plan in place at the time I became involved in Ms. Mills' care was to defer cardiac catheterization until receipt of the pending COVID-19 test results.

10. Based upon multiple factors including, but not limited to, my examination and assessment of Ms. Mills on March 22, 2020, the timing of the assessment, and Ms. Mills' history, presentation, symptoms, and test results, I, in good faith, agreed with the plan to defer cardiac catheterization until a COVID-19 infection was ruled out as is detailed in

my contemporaneously created note of March 22, 2020 which is attached hereto.

11. COVID-19 was a primary factor in my diagnostic assessment of COVID-19 caused myocarditis versus acute coronary syndrome.

12. The medical records indicate that on March 21, 2020 at approximately 5:18 pm, a polymerase chain reaction ("PCR") COVID-19 test was administered to Ms. Mills, and the collected specimen was sent to the Connecticut Department of Public Health for testing.

Brett H. Duncan, MD

STATE OF CONNECTICUT)
) ss. _____
COUNTY OF)

Subscribed and sworn to before me, this 12th day of January, 2021.

~~Notary Public~~
~~My Commission Expires~~:
Commissioner of the Superior Court

DOCKET NO.: HHD CV20 6134761 S	:	SUPERIOR COURT
ESTATE OF CHERYL D. MILLS	:	J.D. OF HARTFORD
V.	:	AT HARTFORD
HARTFORD HEALTHCARE CORP., ET AL.	:	MAY 12, 2021

AFFIDAVIT

I, **Brett H. Duncan, MD**, being duly sworn, depose and say that:

1. I am over the age of eighteen years and believe in the obligation of an oath.

2. I am board-certified in cardiovascular disease and a licensed physician in the State of Connecticut, and I had privileges to provide care and treatment to patients at Hartford Hospital during the timeframe at issue in this lawsuit.

3. I make this affidavit in support of a Motion to Dismiss filed on my behalf. This affidavit is based on my own personal knowledge, as well as my review of certain medical records produced during or otherwise relating to the treatment period at issue in this lawsuit.

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5. As of the time I became involved in the care and treatment of Ms. Mills, the plan in place was to defer cardiac catheterization until receipt of the

pending COVID-19 test results as her presentation was consistent with COVID-19 related myocarditis, and an active COVID-19 infection had to be ruled out.

6. The existing treatment plan in place at the time of my involvement in Ms. Mills' care did not include urgent or emergent transfer to the catheterization lab upon receipt of a negative COVID-19 test.

Brett H. Duncan, MD

STATE OF CONNECTICUT)
) ss. _____
COUNTY OF)

Subscribed and sworn to before me, this 12th day of May, 2021.

Notary Public
My Commission Expires:
Commissioner of the Superior Court

ED Notes

[redacted]

History of Present Illness

Patient is a 63 y.o. female who presents to the emergency department with the chief complaint of a sore throat and headache. The patient denies any chest pain however tells staff she has a murmur and needs a valve replacement. The pt denies SOB. Denies pain in neck, jaw or extremities.

Primary Assessment

[redacted]

Cardiovascular: Irregular rate and rhythm, denies chest pain.
Respiratory: Airway patent, open and clear, regular depth and pattern, unlabored. Equal chest expansion. No cough or shortness of breath reported.
[redacted]

Exposure: Clothing removed, blanket and warm environment provided.
Vital Signs: BP (!) 153/76 (BP Location: Left arm, Patient Position: Sitting) | Pulse (!) 146 | Temp 98.6 °F (37 °C) (Oral) | Resp 20 | Ht 1.524 m (5') | Wt 90.7 kg (200 lb) | SpO2 97% | BMI 39.06 kg/m²
Pain Assessment: 8/10 headache

[redacted]

ED Notes (continued)

ED Provider Notes by Theresa M Adams, MD at 3/21/2020 12:02 PM (continued)

Skin: Skin is warm and dry.
Neurological:
She is alert and oriented to person, place, and time. She exhibits normal muscle tone.
Psychiatric: Thought content normal.
Nursing note and vitals reviewed.

ED Course

MDM:

Clinical Impression Notes:
63-year-old female presenting to the ED complaining of sore throat and headache for the past 3 days. She states her granddaughter had strep throat recently. Her throat is not significantly erythematous, and no exudate. Rapid strep test is performed. I will give the patient a viscous lidocaine treatment as well as Decadron. She is noted to be tachycardic and I did order IV fluids. Patient was placed on a cardiac monitor and noted to be in rapid A. fib. An EKG is obtained.

12:08 PM–I was handed the patient's EKG and she was noted to be very tachycardic and irregular on the heart monitor. It shows a rapid A. fib with evidence of an inferolateral ST elevation MI. STEMI alert was called and the patient was given aspirin and Brilinta. Reconfirm with the patient that she is not having any chest pain or shortness of breath. She states that she is having sore throat not neck pain. She denies any arm or back pain. She is quite anxious, and resistant to my concerns that she may be having an MI. She does have a copy of her old EKG from her cardiologist Dr Kevin Dougherty in Glastonbury from 3 weeks ago. It shows sinus rhythm with a heart rate of 79, there are some ST depressions noted laterally, and slight elevation in aVR. There are no STEMI criteria present on that EKG.

12:12 PM - I spoke with transfer center at Hartford hospital. They connected me with Dr. Asad Rizvi, the on-call Cath Lab attending. He felt that the patient did not meet criteria to be taken immediately to the Cath Lab as her symptoms of sore throat and headache did not seem consistent with a STEMI to him. He was concerned about COVID-19, however the patient has no cough, shortness of breath, or fever. I have Tiger texted him a copy of her EKG as well as a previous EKG from her cardiologist 3 weeks ago. As of now, he recommends aspirin but no heparin until the patient can undergo an echo. I have ordered esmolol for rate control since it can be titrated off easily if BP drops.

12:30 PM– Troponin is 8.6 via I-stat.

12:33 PM–I spoke with CLC in an attempt to speak with the interventional cardiologist. She states she would pass on the message that the patient's troponin is 8.6. He did review via Tiger text her previous EKG from March 2, as well as the troponin level and states he would still like her to go to the ED.

Critical Care:
Critical Care: The patient was critically ill with a high probability of imminent or life threatening deterioration. I spent greater than 30 minutes of discontinuous time evaluating the patient,delivering critical care at the bedside, discussing and evaluating pertinent data with housestaff or consultants. Critical care time does not include time spent performing separately billable procedures or teaching. Total time spent performing critical

ED Notes

[redacted]

History

Chief Complaint

Patient presents with

- Abnormal ECG

HPI

63-year-old female with a history of diabetes, hypertension, asthma, aortic stenosis that needs AVR, initially presenting to Backus hospital with 3-day history of sore throat and headache. Transferred here on esmolol drip after EKG was suggestive of infero-lateral STEMI, trop 8. Cath lab was notified PTA, they thought presentation was more likely to be myo/pericarditis rather than ischemic. Patient received ASA 324mg, but did not receive heparin for this reason. On arrival to our ED, patient feels well, again denies CP, SOB, cough.

She is a registrar at Backus ED and notes sick contacts.

Past Medical History:

Diagnosis — Date

[redacted]

- Aortic valve disease
  PT REPORTS NEEDS REPLACEMENT

[redacted]

[redacted]

[redacted]

Laterality Date

[redacted]

Review of Systems
Constitutional: Negative for chills and fever.
HENT: Positive for ear pain and sore throat. Negative for trouble swallowing and voice change.
Respiratory: Negative for cough and shortness of breath.
Cardiovascular: Negative for chest pain, palpitations and leg swelling.
Gastrointestinal: Negative for abdominal distention, abdominal pain, diarrhea, nausea and vomiting.
Genitourinary: Negative for difficulty urinating and dysuria.
Musculoskeletal: Positive for neck pain. Negative for myalgias.
Neurological: Positive for headaches. Negative for weakness.

Physical Exam

BP 120/74 (BP Location: Left arm, Patient Position: Sitting) | Pulse 78 | Temp 98.4 °F (36.9 °C) (Tympanic) | Resp 18 | SpO2 98%

Physical Exam
Constitutional: Obese, well appearing in no apparent distress
Head: Normocephalic, atraumatic
Eyes: Pupils equal, round, and reactive to light. Extraocular movements intact. No scleral icterus. Conjunctivae normal
ENT: Normal voice, handling secretions appropriately. Oropharynx moist and clear, no erythema or exudate
Neck: No jugular venous distension, trachea midline
Chest wall: No tenderness to palpation, crepitus, or rash
CV: Regular rate and rhythm, murmur appreciated. No friction rub. Intact distal pulses
Respiratory: Clear to auscultation bilaterally, normal effort
Abdomen: Soft, non-tender, non-distended, no pulsatile mass
MSK: Moving all extremities, no edema
Skin: Warm and well perfused
Neuro: Alert and Oriented x3, no focal neurological deficits
Psych: Appropriate behavior

ED Course

MDM
63F who is a registrar at Backus ED, + sick contacts, pmh DM, HTN, asthma, aortic stenosis presenting as a transfer with concern for infero-lateral STEMI, trop 8. Patient initially presented d/t sore throat and headache. She has not had CP, SOB, or cough. Arrives on an esmolol drip after having received ASA 324mg. VSS, physical exam benign. Repeat EKG shows II, III, aVF, V4-V6 with TWI and changes from prior EKG at Backus, indicating dynamic changes. Discussed with cath lab, they saw patient and feel that it is myopericarditis until proven otherwise given absence of CP, SOB. Will repeat labs, dc esmolol drip, and obtain STAT echo. Will require admission.

4:28 PM
Repeat WBC 13.8, increased from 12.2 earlier today. Hyponatremia to 130, CK 500, BNP 3200, negative pro-Cal, CRP 8.19, negative ESR, troponin elevated to 4 but decreased from prior. Admitting to cards SD, Dr. Ferraro-Borgida notified, will let me know which attending to assign patient to.

Echocardiogram Comprehensive

[redacted]

ED Notes by Zacharie Goodreau, RN at 3/21/2020 3:28 PM

Author: **Zacharie Goodreau, RN** | Service: — | Author Type: **Registered Nurse**
Filed: **3/21/2020 3:28 PM** | Date of Service: **3/21/2020 3:28 PM** | Status: **Signed**
Editor: **Zacharie Goodreau, RN (Registered Nurse)**

Echo bedside

Zacharie Goodreau, RN
03/21/20 1528

Electronically Signed by Zacharie Goodreau, RN on 3/21/2020 3:28 PM

ED Notes by Zacharie Goodreau, RN at 3/21/2020 3:07 PM

Author: **Zacharie Goodreau, RN** | Service: — | Author Type: **Registered Nurse**
Filed: **3/21/2020 3:09 PM** | Date of Service: **3/21/2020 3:07 PM** | Status: **Signed**
Editor: **Zacharie Goodreau, RN (Registered Nurse)**

This RN closed patients door and explained need for isolation and patient states "well if you are going to close that door then i'm walking out of here." Will make provider aware.

Zacharie Goodreau, RN
03/21/20 1509

Electronically Signed by Zacharie Goodreau, RN on 3/21/2020 3:09 PM

ED Notes by Zacharie Goodreau, RN at 3/21/2020 2:57 PM

Author: **Zacharie Goodreau, RN** | Service: — | Author Type: **Registered Nurse**
Filed: **3/21/2020 2:58 PM** | Date of Service: **3/21/2020 2:57 PM** | Status: **Signed**
Editor: **Zacharie Goodreau, RN (Registered Nurse)**

I have acknowledged/accepted the hand off of care for this patient. Pt resting comfortably on stretcher. Cardiac monitoring in place. A/ox4, RR even and unlabored, breathing with ease on RA. Appears in NAD. Will continue to assess

Zacharie Goodreau, RN
03/21/20 1458

[redacted]

Consults - Encounter Notes (continued)

Consults by Asad A Rizvi, MD at 3/21/2020 3:27 PM (continued)

Head neck examination: No JVD
Lungs clear to auscultation
Cardiac exam: Normal first and second heart sound with systolic ejection murmur
Abdomen: Soft nontender no pulsatile masses
Extremities warm well perfused
ECG: As described
Impression:
Viral syndrome with myopericarditis
Very low suspicion for plaque rupture/STEMI
Recommendations:
Would place patient in isolation and rule out infectious etiology including Covid 19
Check echo to assess LV and RV function as well as valvular structure and function
Further recommendations once we have echo results.

Electronically Signed by Asad A Rizvi, MD on 3/21/2020 3:35 PM
Electronically Signed by Asad A Rizvi, MD on 3/21/2020 4:38 PM

Consults by John R McArdle, MD at 3/22/2020 5:52 AM

Author: John R McArdle, MD
Filed: 3/22/2020 9:44 AM
Editor: John R McArdle, MD (Physician)
Service: Pulmonology
Date of Service: 3/22/2020 5:52 AM
Author Type: Physician
Status: Signed

Critical Care Progress

Assessment & Plan

[redacted] is a 63 y.o. female who is critically ill/injured and/or remains at high risk for life threatening complications requiring critical care management given the following acute conditions and comorbid processes:

Active Problems:
Pharyngitis, rule out novel human coronavirus infection
Atrial fibrillation with rapid ventricular response
Likely acute myocarditis
Acute MI
Severe aortic stenosis in setting of bicuspid valve
[redacted]

Total LOS: 1 days

Plan by system

Neuro:
CAM: Delirium Present: Negative
Richmond Agitation Sedation Scale (RASS) / Modified RASS: 0-->alert and calm

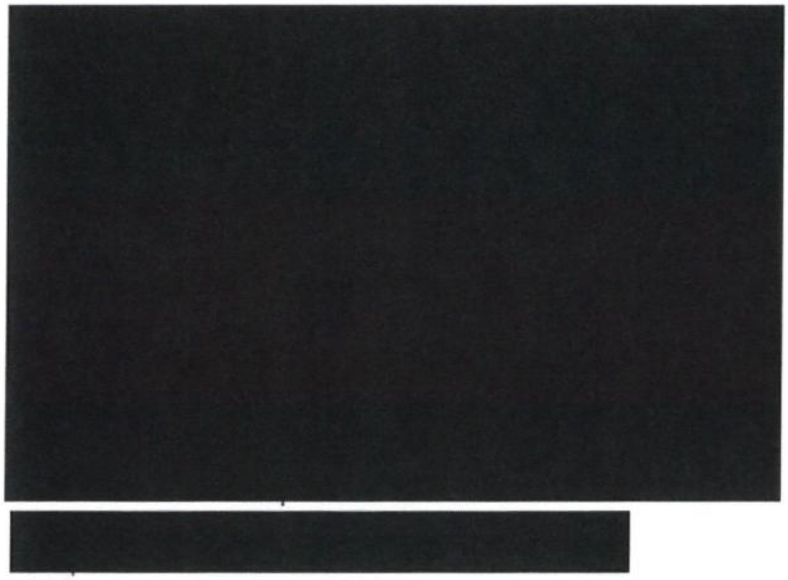
Consults - Encounter Notes (continued)

Consults by John R McArdle, MD at 3/22/2020 5:52 AM (continued)

No acute issues
Avoid nonsteroidal anti-inflammatories

Resp:
Saturating well on room air

CV:
Troponin peaked at 21, now downtrending. Follow EKG.
Continue heparin infusion
Continue metoprolol for rate control- metoprolol 50 mg q 8h
Continue aspirin and statin
Continue Brillinta
Cardiology is primary service
>Echo: Mild to moderate mitral regurgitation, aortic stenosis of unspecified severity, left ventricular ejection fraction 45%, distal septum, apex, and distal lateral wall are akinetic


[redacted]

Net **70 ml**

Endo:
Glargine and sliding scale insulin

Heme/Onc:
Leukocytosis without evidence for bacterial infection

ID:
Rule out novel human coronavirus, suspicion low
>Antibiotics:

Drips: heparin (porcine) IV infusion - low dose protocol, 11 Units/kg/hr, Last Rate: 11 Units/kg/hr (03/21/20 1829)

[redacted]

Progress Notes by Jennifer Martin, RN at 3/24/2020 6:59 PM

Author: **Jennifer Martin, RN**
Filed: **3/24/2020 7:01 PM**
Editor: **Jennifer Martin, RN (Registered Nurse)**
Service: **—**
Date of Service: **3/24/2020 6:59 PM**
Author Type: **Registered Nurse**
Status: **Signed**

Received confirmation from CT DPH of COVID-19 test results, results are negative. Epic results will follow. Please discontinue isolation.

Electronically Signed by Jennifer Martin, RN on 3/24/2020 7:01 PM

Progress Notes by Yanghee Christine Stopka at 3/25/2020 10:27 AM

Discharge Orders
No discharge procedures on file.

No future appointments.

Follow-up Providers
No follow-up provider specified.

Active Issues Requiring Follow-up

Incidental hospital findings:none

Test Results Pending at Discharge

Details of Hospital Stay

Presenting Problem/History of Present Illness
The patient was a 63-year-old woman with a history of diabetes, hypertension, and severe aortic stenosis. The patient had been followed by Dr. Kevin Doherty for cardiology. Her previous echocardiogram 6 months ago had demonstrated severe aortic stenosis as well as moderate mitral stenosis and moderate mitral regurgitation. The patient had declined any intervention for her valvular heart disease as she apparently was feeling relatively well. She had no prior ischemic heart disease history. She presented to Hartford hospital with several days of headache and sore throat. She had no apparent fever or any symptoms of chest discomfort. Her EKG however showed new ST elevations in the inferior leads. It was felt that the patient may be having a an acute myocarditis versus an acute coronary syndrome. It was felt that she was at high risk for having the COVID-19 virus and she was subsequently admitted for further evaluation and treatment.

Hospital Course
The patient did rule in for myocardial injury by enzymes. She was in rapid atrial fibrillation but subsequently converted to sinus rhythm. She continued to deny symptoms of dyspnea or chest discomfort. It was recommended that she have a coronary angiogram to evaluate her coronary anatomy based on her risk factors and elevated cardiac enzymes. As she was clinically stable and being ruled out for an acute infection with the novel coronavirus her procedure was deferred awaiting the test results for COVID-19. She did have a cardiac echo which showed a regional inferior wall motion abnormality consistent with a inferior ST segment elevation myocardial infarction. Patient was treated with antiplatelet drugs, IV heparin, and beta-blockers. She

Discharge Summary - Encounter Notes (continued)

Discharge Summary by William J Farrell, MD at 3/25/2020 11:09 AM (continued)

remained symptomatically stable without dyspnea or chest discomfort. 4 days into the hospital course, her Covid 19 test returned as negative and she was scheduled for a coronary angiogram. On the morning of this procedure however the patient had a sudden PEA arrest. The patient had a prolonged CPR resuscitation effort approximately 30 minutes, but at no time did she regain a meaningful blood pressure or stable heart rhythm. The etiology of her arrest was not completely clear but possibly she suffered a mechanical complication of her myocardial infarction including a possible papillary muscle, septal, or free wall rupture.
No notes on file

Inpatient Treatments: anticoagulation: heparin
Consults: cardiology
Procedures:

Diagnostic Studies:

Physical Exam at Discharge
Discharge Condition: death

Last Vitals:
Pulse:92,**Resp:**18,**BP:**102/74,**SpO2:**99 %,**Weight:** 88.4 kg (194 lb 14.2 oz)
Temp Last 24 hrs: No data recorded

William J Farrell, MD
3/27/2020
8:35 AM

Electronically Signed by William J Farrell, MD on 3/27/2020 8:57 AM

H&P - Encounter Notes

H&P by Melissa J Ferraro-Borgida, MD at 3/21/2020 5:12 PM

Author: Melissa J Ferraro-Borgida, MD | Service: Cardiology | Author Type: Physician
Filed: 3/21/2020 6:15 PM | Date of Service: 3/21/2020 5:12 PM | Status: Addendum
Editor: Melissa J Ferraro-Borgida, MD (Physician)
Related Notes: Original Note by Melissa J Ferraro-Borgida, MD (Physician) filed at 3/21/2020 6:14 PM

CARDIOLOGY HISTORY & PHYSICAL

Admit Date: 3/21/2020 2:00 PM
Patient's Primary Care Physician: Pamela L Neumann, APRN

Active Problems:
* No active hospital problems. *

Progress Notes - Encounter Notes (continued)

Progress Notes by William J Farrell, MD at 3/23/2020 10:50 AM

Author: William J Farrell, MD
Filed: 3/23/2020 10:54 AM
Editor: William J Farrell, MD (Physician)

Service: Cardiology
Date of Service: 3/23/2020 10:50 AM

Author Type: Physician
Status: Signed

Cardiology Progress Note

Active Problems:
Myocarditis (HCC) POA: Yes

Assessment & Plan

Assessment/Plan
The patient is a 63-year-old woman with a history of diabetes and critical aortic stenosis. She also has mixed mitral valve disease with moderate stenosis and regurgitation. She now presents with an acute pharyngitis and rapid atrial fibrillation. She had an acute rise in her cardiac enzymes with a troponin level up to 21. EKG shows new inferolateral ST segment elevations consistent with an acute coronary syndrome or possible pericarditis/myocarditis. Cardiogram shows wall motion abnormalities involving the inferolateral and posterior wall.

Despite this she is hemodynamically stable. She is asymptomatic with no signs of heart failure or ongoing chest pain. Her atrial fibrillation is resolved and she is now in sinus rhythm. She is on appropriate medical therapy. The patient had previously declined any type of intervention for her valvular heart disease. Once she is ruled out for Covid 19 infection she will undergo a right and left heart cath. Patient is frustrated by the delay but understands the rationale for infectious disease evaluation in advance of further procedures. We will continue her on current medications including her beta-blocker, dual antiplatelet therapy, statin therapy, and IV heparin.

Subjective

Patient denies any dyspnea or chest pressure

Objective

Last Vitals
Pulse:84,Resp:18,BP:(I) 146/77,SpO2:100 %,Weight:88.4 kg (194 lb 14.2 oz)
Temp Last 24 hrs: Temp Min: 97.4 °F (36.3 °C) Max: 99.6 °F (37.6 °C)

Intake/Output Summary (Last 24 hours) at 3/23/2020 1050
Last data filed at 3/23/2020 1018

	Gross per 24 hour
Intake	516.16 ml
Output	1000 ml
Net	**-483.84 ml**

Physical Exam:

CONSTITUTIONAL: Well nourished, pleasant and comfortable without distress.
HEENT: unremarkable without jaundice or pallor.
NECK: supple and jugular venous pressure looks normal.
VASCULAR: carotids 2+ upstrokes without bruits. Extremities without clubbing cyanosis or edema.
LUNGS and RESPIRATORY: chest is clear P&A without rales or wheezing.
CARDIAC EXAM: Regular rate and rhythm with a 3/6 systolic murmur at the upper sternal border
GI and ABDOMEN: soft, no masses and no bruits.
SKIN: warm and dry, without significant bruising or ecchymosis.
NEUROLOGIC: Alert, oriented x3 and grossly nonfocal moving all extremities.

Relevant data reviewed
Notable labs are:

Lab Results

Component	Value	Date
TNI	9.80 (HH)	03/22/2020
TNI	8.62 (H)	03/21/2020

Lab Results

Component	Value	Date
PROBNP	3,221 (H)	03/21/2020

Lab Results

Component	Value	Date
TNI	9.80 (HH)	03/22/2020
TNI	8.62 (H)	03/21/2020

Lab Results

Component	Value	Date
CKMB	21.6 (H)	03/21/2020

Lab Results

Component	Value	Date
WBC	16.5 (H)	03/23/2020
WBC	9.9	12/01/2012
HGB	11.7	03/23/2020
HCT	35.0	03/23/2020
PLT	300	03/23/2020

Lab Results

Component	Value	Date
NA	135 (L)	03/23/2020
K	3.4	03/23/2020
CL	97 (L)	03/23/2020
CO2	25	03/23/2020

Progress Notes - Encounter Notes (continued)

Progress Notes by William J Farrell, MD at 3/23/2020 10:50 AM (continued)

BUN	26 (H)	03/23/2020
CREAT	0.7	03/23/2020
GLUC	215 (H)	03/23/2020
GLUC	Negative	10/14/2013
GLUC	Negative	10/14/2013

Lab Results

Component	Value	Date
PTT	34	03/21/2020
LABPROT	12.9	03/21/2020
INR	1.1	03/21/2020

Imaging Studies

Other testing:
Normal sinus rhythm with 2 to 3 mm of ST elevations in the inferior lateral leads with associated deep T wave inversions

Sign
William J Farrell, MD
3/23/2020 10:50 AM

Electronically Signed by William J Farrell, MD on 3/23/2020 10:54 AM

Progress Notes by Kathryn Lafleur, PA at 3/23/2020 5:59 AM

Author: Kathryn Lafleur, PA
Filed: 3/23/2020 12:35 PM
Editor: Kathryn Lafleur, PA (Physician Assistant)
Service: Medical Step Down
Date of Service: 3/23/2020 5:59 AM
Author Type: Physician Assistant
Status: Signed

Critical Care Progress Note

Subjective

Overnight:
- Remains on Heparin gtt, PIV partially dislodged, received quick clot and heparin gtt resumed
- Pt remains on Cardiology service
- K/Mg/Phos replaced

Assessment & Plan

Assessment
63 year old woman with history of bicuspid aortic valve with moderate stenosis, diabetes mellitus, hypertension, hyperlipidemia, retinal artery occlusion with right eye blindness presents from Backus Hospital with concern for myocarditis vs STEMI, pending catheterization. 11SD for COVID-19 rule out.

Active Problems:

Progress Notes - Encounter Notes (continued)

Progress Notes by Jeffrey C Nascimento, DO at 3/23/2020 7:52 AM (continued)

No results for input(s): PHA, PCO2, PO2, HCO3 in the last 72 hours.

Recent Cultures:

Culture			
Date	Value	Ref Range	Status
03/21/2020			Final

Negative after 1 day

Performed at Hartford Hospital Ancillary Laboratory, Newington, CT CT License 0385
CLIA 07D0094387

Imaging Studies:
Appropriate radiology imaging was reviewed (actual images) and compared to prior where applicable. Specific /additional concerns as highlighted below if appropriate.

Sign:
Jeffrey C. Nascimento, DO
3/23/2020 7:52 AM

Electronically Signed by Jeffrey C Nascimento, DO on 3/23/2020 8:44 PM

Progress Notes by William J Farrell, MD at 3/24/2020 2:03 PM

Author: William J Farrell, MD
Filed: 3/24/2020 2:07 PM
Editor: William J Farrell, MD (Physician)
Service: Cardiology
Date of Service: 3/24/2020 2:03 PM
Author Type: Physician
Status: Signed

Cardiology Progress Note

Active Problems:
Myocarditis (HCC) POA: Yes

Assessment & Plan

Assessment/Plan
The patient remains relatively stable. She has no ongoing dyspnea or chest discomfort. She remains in A. fib with generally good rate control. She has known severe aortic stenosis but is adamantly opposed to any valve intervention. She also has significant mitral valve stenosis and regurgitation. The plan is to proceed with a left heart cath and potential PCI based on her anatomy pending a rule out for culprit 19. Patient is not having any active anginal symptoms. He is amenable to a PCI procedure if this proves necessary but is not willing to stay for bypass surgery or any type of valve intervention at this time. She remains on IV heparin. Increase her metoprolol to 100 mg twice daily for additional rate control. We could also add digoxin if necessary for heart rate control.

Subjective

The patient denies any dyspnea, palpitations, or chest discomfort at rest

Objective

Last Vitals
Pulse:(!) 120,Resp:18,BP:104/62,SpO2:99 %,Weight:88.4 kg (194 lb 14.2 oz)
Temp Last 24 hrs: Temp Min: 97.1 °F (36.2 °C) Max: 99.4 °F (37.4 °C)

Intake/Output Summary (Last 24 hours) at 3/24/2020 1403
Last data filed at 3/23/2020 1905

	Gross per 24 hour
Intake	130 ml
Output	—
Net	**130 ml**

Physical Exam:

CONSTITUTIONAL: Well nourished, pleasant and comfortable without distress.
HEENT: unremarkable without jaundice or pallor.
NECK: supple and jugular venous pressure looks normal.
VASCULAR: carotids 2+ upstrokes without bruits. Extremities without clubbing cyanosis or edema.
LUNGS and RESPIRATORY: chest is clear P&A without rales or wheezing.
CARDIAC EXAM: Irregular with a 3/6 systolic murmur
GI and ABDOMEN: soft, no masses and no bruits.
SKIN: warm and dry, without significant bruising or ecchymosis.
NEUROLOGIC: Alert, oriented x3 and grossly nonfocal moving all extremities.

Relevant data reviewed
Notable labs are:
Lab Results

Component	Value	Date
TNI	9.80 (HH)	03/22/2020
TNI	8.62 (H)	03/21/2020

Lab Results

Component	Value	Date
PROBNP	3,221 (H)	03/21/2020

Lab Results

Component	Value	Date

[redacted]

H&P - Encounter Notes

H&P by Melissa J Ferraro-Borgida, MD at 3/21/2020 5:12 PM

Author: **Melissa J Ferraro-Borgida, MD** | Service: **Cardiology** | Author Type: **Physician**
Filed: **3/21/2020 6:15 PM** | Date of Service: **3/21/2020 5:12 PM** | Status: **Addendum**
Editor: **Melissa J Ferraro-Borgida, MD (Physician)**
Related Notes: **Original Note by Melissa J Ferraro-Borgida, MD (Physician) filed at 3/21/2020 6:14 PM**

CARDIOLOGY HISTORY & PHYSICAL

Admit Date: 3/21/2020 2:00 PM
Patient's Primary Care Physician: Pamela L Neumann, APRN

Active Problems:
* No active hospital problems. *

Assessment & Plan

Assessment
Suspected acute myocarditis
Pharyngitis - acute viral illness
New onset atrial fibrillation with RVR
Bicuspid aortic valve with moderate AS
Hypertension
Hyperlipidemia
Diabetes mellitus

Plan
Cardiac cath deferred. Despite WMA on echo and STE on ECG, her history is much more consistent with acute myocarditis than ACS. She has no chest pain or dyspnea. Repeat Tn was down trending which is reassuring.
Would trend Tn at HH x 2 more
Start IV heparin for Afib - has no effusion and CHAD2SD2vasc = 6
Culture for COVID, influenza and strep. Maintain in 11SD until COVID ruled out.
Consider cardiac cath if COVID - given WMA on echo but still suspect this is myocarditis
Aspirin, statin, beta blocker for HR
Needs diabetes control
Tylenol for throat pain and headache

Due to current COVID pandemic and in the interest of preserving scarce resources (PPE) and limiting unneccessary exposures to avoid workforce shortages, I did not enter patient room. D. Rizvi examined patient and shared details with me, I reviewed echo images, ECG images, chart. I discussed the case with Alec Freeling, MD in ER via TT as well as Dr. Brian Kohen in ER. Discussed at length with Dr. Rizvi and agree with his assessment and plan. I spoke with the patient for 25 minutes by phone and answered numerous questions for her.

Critical care time spent today 60 minutes.

Subjective

Chief Complaint
Sore throat

History of Present Illness
63 year old woman with history of bicuspid aortic valve with moderate stenosis, diabetes mellitus, hypertension, hyperlipidemia, retinal artery occlusion with right eye blindness. She complains of a sore throat for 2 days without fever or cough or shortness of breath. She denies chest pain. No runny nose although was stuffy, mild toothache (has bad teeth and dentist prescribed erythromycin yesterday. Also notes headache.She works in ER at Backus Hospital and is not sure if she has been exposed to anyone who is currently ill with COVID 19. On arrival in their ER, ECG showed Afib with RVR and ST elevations in the anterolateral and inferior leads. Cath lab was called for consultation for urgent cath.
Dr. Rizvi saw the patient (with PPE due to COVID pandemic). Upon review of patient and data, he deferred

acute cardiac cath due to history more consistent with myocarditis in setting of viral illness than true STEMI. She has been placed in negative pressure room and will be ruled out for COVID on B11SD.

Review of Systems
Constitutional: No fevers, chills, or night sweats.
Neurologic: Headache, prior retinal artery occlusion.
Eyes: Right eye blindness. No change in left eye vision.
HEENT: No hearing loss, no tinnitus.Toothache.
Lungs: Denies cough or shortness of breath.
Heart: No chest pain or dyspnea.
Gastrointestinal: Mild nausea from something she was given in the ER - not sure what. No diarrhea, constipation.
Genitourinary: No hematuria or dysuria.
Skin: No chronic lesions or rashes.
Musculoskeletal: No myalgias. Has bad knees.

Objective

Past History
Past Medical History:

Diagnosis	Date

- Abdominal pain, other specified site
  Abdominal pain of multiple sites: 2014-02-26 00:03:08
- Acute sinusitis, unspecified
  Acute sinusitis: 2014-02-26 00:03:07
- Acute sinusitis, unspecified
  Acute sinusitis: 2014-02-26 00:03:07
- Aortic valve disease
  PT REPORTS NEEDS REPLACEMENT
- Backache, unspecified
  History of backache: 2014-02-26 00:03:07
- Diverticulitis of colon (without mention of hemorrhage)(562.11)
  History of diverticulitis of colon: 2014-02-26 00:03:07
- Hematuria, unspecified
  History of hematuria: 2014-02-26 00:03:06
- Herpes zoster with other nervous system complications(053.19)
  Postherpetic neuralgia: 2014-02-26 00:03:07
- Herpes zoster without mention of complication
  History of herpes zoster: 2014-02-26 00:03:07
- Hyperlipidemia
- Hypertension
- Type II or unspecified type diabetes mellitus without mention of complication, not stated as uncontrolled
  Poorly controlled diabetes mellitus: 2014-02-26 00:03:08
- Unspecified asthma(493.90)
  Asthmatic bronchitis: 2014-02-26 00:03:08

H&P - Encounter Notes (continued)

H&P by Melissa J Ferraro-Borgida, MD at 3/21/2020 5:12 PM (continued)

- **glimepiride (AMARYL) 2 MG tablet, Take 1 tablet (2 mg total) by mouth 2 (two) times a day., Disp: 180 tablet, Rfl: 1**
- **Glucose Blood (BAYER CONTOUR TEST VI), Bayer Contour Test In Vitro Strip USE 1 STRIP 3 TIMES DAILY. ; Start Date: 11/14/2012; End Date:, Disp: , Rfl:**
- **ibuprofen (MOTRIN) 600 MG tablet, Take 1 tablet (600 mg total) by mouth 3 times daily (every 8 hours) as needed for mild pain., Disp: 90 tablet, Rfl: 1**
- **latanoprost (XALATAN) 0.005 % ophthalmic solution, , Disp: , Rfl:**
- **metFORMIN (GLUCOPHAGE-XR) 500 MG 24 hr tablet, Take 2 tablets (1,000 mg total) by mouth 2 (two) times a day. Swallow whole. Do not crush, break or chew., Disp: 360 tablet, Rfl: 1**
- **metoPROLOL SUCCINATE (TOPROL-XL) 100 MG 24 hr tablet, Metoprolol Succinate ER 100 MG Oral Tablet Extended Release 24 Hour ; Start Date: 9/24/2013; End Date:, Disp: , Rfl:**
- **nystatin (MYCOSTATIN) 100000 UNIT/GM cream, Apply topically 2 (two) times a day. Apply to affected area, Disp: 30 g, Rfl: 1**
- **oxyCODONE-acetaminophen (PERCOCET) 5-325 mg per tablet, Take 1-2 tablets by mouth 3 times daily (every 8 hours) as needed for moderate pain. Max Daily Amount: 6 tablets, Disp: 60 tablet, Rfl: 0**
- **PAZEO 0.7 % ophthalmic solution, , Disp: , Rfl: 0**
- **valsartan-hydrochlorothiazide (DIOVAN HCT) 320-25 MG per tablet, Diovan HCT 320-25 MG Oral Tablet ; Start Date: 11/6/2012; End Date:, Disp: , Rfl:**

Physical Exam

Last Vitals: Pulse:84, **Resp**:18, **BP**:BP Min: 80/60 Max: 153/76 **MAP**: **SpO2**:99 % **CVP**:
Temp Last 24 hrs: Temp Min: 98.4 °F (36.9 °C) Max: 98.6 °F (37 °C)

Physical exam not performed: Dr. Rizvi from cath lab examined patient with PPE on and discussed entire case with me. In order to preserve PPE in midst of COVID crisis and to avoid redundant exposures will defer PE until COVID ruled out.

Relevant data reviewed
Results from last 7 days

Lab	Units	03/21/20 1409	03/21/20 1214
WHITE BLOOD CELL COUNT	Thou/uL	13.8*	12.2*
HEMOGLOBIN	g/dL	11.5*	12.3
HEMATOCRIT	%	35.3	37.6
MCV	fL	87	86
PLATELET COUNT	Thou/uL	219	229

Results from last 7 days

H&P - Encounter Notes (continued)

H&P by Melissa J Ferraro-Borgida, MD at 3/21/2020 5:12 PM (continued)

Lab	Units	03/21/20 1409	03/21/20 1214
GLUCOSE	mg/dL	312*	255*
CALCIUM	mg/dL	8.8	9.4
SODIUM	mmol/L	130*	131*
POTASSIUM	mmol/L	4.1	3.6
CO2	mmol/L	18*	21*
CHLORIDE	mmol/L	95*	93*
BUN	mg/dL	15	15
CREATININE	mg/dL	0.7	0.7

Results from last 7 days

Lab	Units	03/21/20 1409
PROBNP, N-TERMINAL	pg/mL	3,221*

Results from last 7 days

Lab	Units	03/21/20 1409	03/21/20 1214
TROPONIN I, POC	ng/mL	--	8.62*
TROPONIN I	ng/mL	4.28*	--

Imaging Studies
Echo: Summary
This is a bedside tablet-based study for a suspected or confirmed COVID-19 patient. A limited number of images were obtained.
The left atrium is dilated.
Wall thickness is increased. The distal septum and apex and distal lateral wall are akinetic. Left ventricular systolic function is mildly
reduced.
Estimated left ventricular ejection fraction is 45%.
There is aortic stenosis of undetermined severity. There is mild aortic regurgitation.
There is mild to moderate mitral regurgitation.
No previous study is available for comparison.
Findings

ECG: Afib with RVR, marked ST elevations in anterolateral and inferior leads with ST depression high lateral leads.

Sign
Melissa J Ferraro-Borgida, MD

[redacted]

Progress Notes - Encounter Notes

Progress Notes by Melissa J Ferraro-Borgida, MD at 3/22/2020 12:24 AM

Author: Melissa J Ferraro-Borgida, MD
Filed: 3/22/2020 12:39 AM
Editor: Melissa J Ferraro-Borgida, MD (Physician)
Service: Cardiology
Date of Service: 3/22/2020 12:24 AM
Author Type: Physician
Status: Signed

Patient transferred from ER to B11SD.

Tn went from 8.62(at noon) to 4.28 (at 2pm) and back up to 21 84 (at 21:29)

.

She remains chest pain free as she has been all along.
ECG now with SR and persistent inferolateral and anterior ST elevations. T waves are now inverting. Her only symptoms have been sore throat with difficulty swallowing and headache and toothache.

There is a note from Dr. Dougherty on 3/2/2020 stating that her AS is critically severe with moderate MR/MS. There was basilar posterior hypokinesis on prior echo.

He had had a long discussion with her regarding her valvular and likely coronary disease. She adamantly refused open heart surgery and despite his persistence, she refused structural heart team consult for consideration of SAVR.

She will need full echo for evaluation of valves and cardiac cath to assess coronary anatomy.

Continue IV heparin, aspirin, statin, BB. No nitrates with critical AS.

She will need AC on D/C for PAF and CHADS2vasc = 6.
Communicated plan with B11SD team.

[redacted]

Progress Notes by Brett H Duncan, MD at 3/22/2020 9:08 AM

Author: Brett H Duncan, MD
Filed: 3/22/2020 9:17 AM
Editor: Brett H Duncan, MD (Physician)

Service: Cardiology
Date of Service: 3/22/2020 9:08 AM

Author Type: Physician
Status: Signed

Cardiology Progress Note

CARDIOLOGY P.C.
HARTFORD CT

860-522-5712

Active Problems:
Myocarditis (HCC) POA: Yes

Assessment & Plan

Assessment

1. Troponin elevation most consistent with myocarditis
2. COVID testing pending
3. Pharyngitis
4. Severe bicuspid aortic stenosis
5. PAF with spontaneous conversion to sinus rhythm
6. Hypertension

Plan

Interesting enzyme release. Typically with non-revascularized atherosclerotic events there will be a 2-3-day peak CPK and in this case CPK already trending downward as his troponin. While atherosclerotic disease is still in the differential diagnosis the story is still most consistent with myocarditis. Waiting for COVID testing to become negative but do suggest cardiac catheterization before hospital discharge

1. Metoprolol tartrate 50 mg 3 times daily
2. In the absence of evidence of pericardial effusion it would be reasonable to continue IV heparin/Brilinta
3. Monitor for ventricular tachyarrhythmias
4. Cardiac catheterization before hospital discharge
5. We will have to hold ARB until COVID testing completed
5. High-dose statin therapy
6. Spironolactone 25 mg daily

Subjective

Very frustrated about being in the hospital. Very frustrated about not having cardiac catheterization. I explained everything. She is had absolutely no chest symptoms. Primary compliant is pharyngitis symptoms.

Objective

Last Vitals: Pulse:86, **Resp**:18, **BP**:BP Min: 122/78 Max: 177/84 **MAP**: **SpO2**:98 % **Temp Last 24 hrs:** Temp Min: 97.5 °F (36.4 °C) Max: 99.8 °F (37.7 °C)
Telemetry: Sinus rhythm with occasional PVCs

Intake & Output:

Intake/Output Summary (Last 24 hours) at 3/22/2020 0909
Last data filed at 3/22/2020 0800

	Gross per 24 hour
Intake	359.71 ml
Output	350 ml
Net	**9.71 ml**

Weight trend:
Wt Readings from Last 3 Encounters:

03/22/20	88.4 kg (194 lb 14.2 oz)
03/21/20	90.7 kg (200 lb)
12/16/19	83.9 kg (185 lb)

Physical Exam

General Appearance: alert and oriented ×3, no distress, appears stated age
Neck: no carotid bruit, JVD 6
Lungs: Clear to auscultation bilaterally, respirations unlabored
Chest Wall: No tenderness or deformity
Heart: PMI-diffuse, regular rate and rhythm, S1, S2 normal, 2/6 aortic stenosis murmur, ejection click noted, positive S4 no S3, no rub
Abdomen: Soft, non-tender, bowel sounds active, no masses, noHepatomegally
Extremities: no cyanosis, no edema, warm to touch
Pulses: Dorsalis Pedis: present
Neurologic: Normal motor and sensory exam.